



AMERICAN
PSYCHOLOGICAL
ASSOCIATION
PRACTICE ORGANIZATION

January 26, 2016

The Honorable Johnny Isakson
131 Russell Senate Office Building
United States Senate
Washington DC, 20510

The Honorable Mark Warner
475 Russell Senate Office Building
United States Senate
Washington DC, 20510

Dear Senators Isakson and Warner:

The American Psychological Association Practice Organization (APAPO) appreciates the opportunity to provide comments to the Senate Finance Committee Chronic Care Working Group in response to the Policy Options Document issued by the Working Group in December 2015. The APAPO is dedicated to advancing the practice of psychology and represents the interests of doctoral-trained psychologists, who are licensed health care professionals. The APAPO is an affiliate of the American Psychological Association (APA), the largest scientific and professional organization representing psychology in the United States. The APA's membership includes more than 122,500 clinicians, researchers, educators, consultants, and students.

We share the Committee's concern with the need to better address the health care needs of Medicare beneficiaries with chronic conditions, and we applaud the Working Group's recognition of the critical importance of mental and behavioral health care in any such effort. As we noted in our letter to you dated June 22, 2015, any such initiative, if it hopes to be successful, must address chronic mental health disorders in addition to chronic medical diseases. The Centers for Medicare and Medicaid Services (CMS) estimate that more than 16 percent of Medicare beneficiaries suffer from depression, which is more than suffer from heart failure, cancer, or Alzheimer's disease.ⁱ The rate of suicide for Americans aged 65 and older is roughly twice as high as for those under age 25.ⁱⁱ Unfortunately, only 3.9% of Medicare spending is on mental health services -- less than any other private or public insurance program.ⁱⁱⁱ

As the Working Group has also recognized, the Medicare program must better address the high rate of comorbidity of mental disorders with chronic medical conditions. An estimated 68% of adults with mental disorders have comorbid medical conditions, and 29% of adults with medical conditions have mental disorders.^{iv} Patients with a comorbid mental health disorder and medical disease are highly expensive to treat. Medicare beneficiaries, for example, with depression and a comorbid diagnosis of diabetes and/or congestive heart failure (CHF) had treatment costs 67% higher than those with only diabetes and/or CHF.^v Behavioral health affects physical health, and optimal outcomes can only be achieved if mental health services are an integral part of the service delivery system.

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By improving access to effective mental health services for Medicare beneficiaries with chronic conditions, the following steps would further the Committee's bipartisan goals of increasing care coordination and improving care transitions, facilitating the delivery of high quality care, producing stronger patient outcomes, and contributing to reduced growth in Medicare spending.

Address the Need for Behavioral Health among Chronically Ill Beneficiaries by Eliminating Unnecessary Requirements that Hinder Access to Psychologists' Services.

We applaud the Working Group's recognition of the critical need to expand and improve Medicare beneficiaries' access to mental and behavioral health care services. Psychologists are leading providers of mental, behavioral, and diagnostic care, providing more than half of all psychiatric diagnostic evaluations, roughly half of all individual and family psychotherapy, and virtually all neuropsychological testing services and health and behavioral assessments and interventions to Medicare beneficiaries. Psychologists provide these critical services in a range of settings, including hospitals and hospital outpatient departments, psychiatric hospitals, partial hospital programs, comprehensive outpatient rehabilitation facilities, skilled nursing facilities, rural health clinics, and federally qualified health centers.

Psychologists, however, are leaving Medicare due to inappropriate and unnecessary physician supervision requirements. In many facility-based treatment settings, Medicare requires physician oversight of psychologists, which can cause beneficiaries to be denied access to appropriate and timely psychological care due to the lack of availability of such oversight. The problem is particularly acute in rural and frontier areas where there are few physicians available to oversee care.

This obstacle to beneficiaries' access to needed mental health care is particularly unfortunate given that it is unnecessary -- psychologists are licensed to practice without physician supervision in all 50 states and other U.S. jurisdictions. Psychologists, in fact, practice independently in all private sector health plans, Medicare Advantage plans, the Veterans Health Administration, and TRICARE. In traditional Medicare, however, these outdated requirements remain, hindering beneficiary access to needed psychological services and driving psychologists out of the program.

The most efficient way to remove these unnecessary requirements is to add psychologists to Medicare's definition of a "physician" (section 1861(r) of the Social Security Act), which already includes chiropractors, dentists, optometrists and podiatrists. Including psychologists in the "physician" definition would allow them to provide the services for which they are fully trained and licensed. It would not reconstitute them as physicians or expand their scope of practice, as changes in scope of practice can only occur through changes to state licensing laws.

Your colleague on the Committee, Senator Sherrod Brown (D-OH), introduced the ***Medicare Mental Health Access Act (S. 1064)*** in the 113th Congress to improve beneficiaries' access to mental health services by adding psychologists to the definition of "physician." We continue to work with Senator Brown with the expectation that the bill will be reintroduced in the current

Congress in the very near future. The bill has been reintroduced in the House of Representatives (H.R. 4277) by Representatives Kristi Noem (R-SD) and Jan Schakowsky (D-IL).

The clear and recognized need for improved mental and behavioral health care among Medicare beneficiaries, and the much higher treatment costs associated with comorbid mental health and chronic medical conditions, clearly argue for greater access to psychologists' services. By removing the outdated and unnecessary physician supervision requirements, the Medicare Mental Health Access Act would improve that access for chronically ill Medicare beneficiaries (and others) and would eliminate a key problem driving psychologists out of the program.

An actuarial analysis of the bill determined that including psychologists in the "physician" definition will not significantly increase Medicare claims costs. Medicare Advantage plans have not experienced cost increases by allowing psychologists to practice without physician oversight, and existing program requirements would remain in place to ensure that the all services provided are medically necessary and appropriate.

We recommend that the Committee address the critical mental and behavioral health care needs of Medicare beneficiaries, especially those with chronic conditions, by including the provisions of the Medicare Mental Health Access Act in any chronic care legislation the Committee may consider.

Fully Integrate Health and Mental Health Services and Include Multi-professional Care.

Numerous studies indicate that mental and behavioral health problems dramatically increase treatment costs for patients with chronic medical conditions. The co-location and full integration of mental health professionals into primary care teams are among the most effective ways to reduce those costs, particularly emergency department and inpatient medical costs. Integrating mental and behavioral health services into primary care settings and the patient centered medical home is also critical to improving health outcomes for patients with chronic medical conditions, as well as for those with depression or other mental health disorders. Thirty percent of primary care patients with chronic medical conditions have comorbid mental health or substance use disorders, and only one in eight patients receives evidence-based mental health treatment.^{vi} Despite the substantial value of having psychologists and other behavioral health care providers integrated into primary care settings, significant financial disincentives and reimbursement issues still present formidable barriers to their participation.

Most individuals who receive mental health treatment get help from a primary care provider, rather than from a mental health professional.^{vii} An abundance of data, however, suggests that the typical primary care intervention for patients with mental health problems falls short of the mark due in part to the limited knowledge of primary care providers regarding mental and behavioral health problems.^{viii} Primary care providers usually treat mental disorders by writing prescriptions for psychotropic drugs, despite the fact that psychotherapy is frequently as effective as those drugs, and that there are potentially dangerous side effects associated with medication use. Older adults in particular are more likely to experience drug toxicity because of reduced metabolism of medications, which can lead to other health problems (*e.g.*, lethargy, confusion,

falls, delirium, and death) along with increased healthcare costs and service utilization.^{ix} In addition, research shows that older adults have a preference for psychotherapy instead of medication to treat these disorders.^x It is critical that psychologists and other mental health professionals be included in integrated health care teams in order to reduce these drug toxicity problems, provide patients with appropriate treatment choices, and address mental health knowledge gaps in the primary care setting.

As part of integrated health care teams, psychologists provide a wide range of interventions to improve patient health, including diagnosis, assessment, consultation, testing, case management, health and behavioral interventions, and psychotherapy. These services address both health psychology matters (*e.g.*, self-management of diabetes, asthma, healthy diet, and smoking cessation programs) and treatment for mental disorders (*e.g.*, depression and anxiety). The use of effective, evidence based psychotherapy, such as cognitive therapy and problem solving therapy, not only improves outcomes and reduces service costs, it also reduces pharmacy costs. Psychologists also play other crucial roles in collaborative care models, such as developing and evaluating the models, training the staff, and functioning as consultants.

We are pleased that Medicare policies are in place to encourage clinical psychologists to practice in accountable care organizations (ACOs). Engaging psychologists in ACOs and other coordinated care models being formed and tested by the CMS Innovation Center will help ensure greater beneficiary access to appropriate mental and behavioral health services.

Improve Care Management Services for Individuals with Multiple Chronic Conditions by Allowing Appropriate Psychologist Reimbursement.

We appreciate the Working Group's focus on the important issue of chronic care management (CCM) for Medicare beneficiaries. As the Working Group has recognized, patients suffering from chronic conditions benefit greatly from CCM services, including care coordination, transition care management, assistance with social services, and monitoring of the patient's ability to adhere to the treatment plan for their disease. Psychologists provide many of these crucial care management services, and spend considerable time dealing with other healthcare providers, family members, caregivers, and social service agencies in order to assist the patient.

Despite this, Medicare will not reimburse psychologists for providing CCM or transitional care management services to Medicare beneficiaries. CMS allows only physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives to bill for those services. Psychologists, however, provide many of the psychotherapy and health and behavior services in Medicare, along with the majority of testing services and development of comprehensive evaluation reports that are often the basis of care plans. With no ability to receive reimbursement for these critical services, psychologists are not being recognized for the work they do when treating patients who suffer from chronic diseases. Along with unnecessary physician supervision requirements and falling reimbursement rates generally, this is one of the issues driving psychologists away from the Medicare program.

We would suggest, therefore, that any chronic care legislation considered by the Committee include provisions allowing psychologists to be reimbursed for CCM and transitional care management services under existing CPT codes (99490 and 99495/99496) as well as under any high-severity CCM code the Working Group may establish.

In its discussion of the proposed high-severity CCM code, the Working Group identified “one chronic condition in conjunction with Alzheimer’s or a related dementia” as a possible patient criterion for the code (Policy Options Document, p.11). We would suggest that this criterion be expanded beyond dementia to take into account beneficiaries suffering from one chronic medical condition and serious mental illness, such as major depressive disorder (especially given its link to exceptionally high rates of suicide in older men).

Allowing psychologists to be recognized for the extensive care management services they provide to Medicare beneficiaries would clearly further the Committee’s goals of increasing care coordination, streamlining Medicare’s payment systems to incentivize the appropriate level of care for beneficiaries with chronic diseases, improving care transitions, and producing stronger patient outcomes.

Include Psychologists in the Expanded Independence at Home Model of Care.

We are pleased the Working Group is considering expansion of the successful Independence at Home (IAH) demonstration program. The IAH program focuses on coordinated, team-based care to improve outcomes and reduce costs for Medicare beneficiaries with multiple chronic conditions. Given the high prevalence of Alzheimer’s, depression, and other mental health conditions among the IAH beneficiary population, psychologists have played a key role in IAH care teams. Psychologists’ evaluation and assessment of the patient and the patient’s home, for example, are often used to generate the home care plan that is implemented.

As the Working Group considers expansion of this program, we believe an examination of the Home Based Primary Care (HBPC) model currently in use in the Department of Veterans Affairs might prove useful. The HBPC program provides health care services to veterans with complex health care needs, in their homes, using inter-professional health care teams. Given the similar goals of the HBPC and IAH programs, we recommend that the Working Group call for a cross-collaborative study or discussion between CMS and the Department of Veterans Affairs in order to identify and exchange best practices of these two programs, to the benefit of both.

We would also encourage the Working Group to highlight the growing diversity of the Medicare population and to promote culturally-competent care models and workforces within an expanded IAH program.

Make Psychologists Eligible for Incentives for the Adoption of Electronic Health Records.

An important element to improve health outcomes for Medicare patients with chronic conditions through integrated care is to encourage the seamless exchange of electronic health records

between primary care and mental health providers. Unfortunately, despite the high prevalence of chronic, co-occurring medical/surgical conditions and mental illness, when the HITECH Act was enacted in 2009 it omitted psychologists and other mental and behavioral health providers (with the exception of psychiatrists) from receiving Medicare and Medicaid incentive payments to adopt electronic health records in their practices. Behavioral health facilities, such as community mental health centers and psychiatric hospitals, were also excluded from eligibility.

Initial investment and ongoing maintenance costs present a significant barrier to electronic health records use for mental and behavioral health care providers, and as a result, very few of these providers participate in the Health Information Exchange. Consequently, Medicare primary care providers and care coordination teams struggle to (1) be informed of their patients' behavioral health disorders and medications, and (2) receive the necessary behavioral health records of their patients in a timely manner, which lowers the quality of care received by Medicare beneficiaries with mental disorders and co-occurring, chronic medical conditions.

Psychologists are the preeminent providers of behavioral health services to Medicare beneficiaries, and as such, should be made eligible for the same electronic health records use incentives available to other providers under the HITECH Act. The inclusion of psychologists and other mental health providers will increase the likelihood that Medicare patients will receive effective, high-quality care, and should also generate savings for the program. Recognizing these providers as "meaningful users" under the law will promote integration of mental health services into primary care settings, reduce adverse drug-to-drug interactions and duplicative tests, and allow hospital emergency departments to triage patients more effectively. In addition, psychology is the profession that develops reliable and valid patient questionnaires and checklists that are widely used by electronic health records systems to gather health information for providers. To advance the use of these systems as a means of provider/patient communication, it is essential that psychologists have ready access to this technology.

We believe that reform of the Meaningful Use program must involve both vigorous enforcement of the interoperability provisions in the Medicare Access and CHIP Reauthorization Act (PL 114-10) as well as enactment of legislation to extend Medicare and Medicaid incentive payments to psychologists and other mental and behavioral health providers and facilities. Given that the incentives made available under the HITECH Act have run their course, we encourage the Committee to consider a new round of incentives focused on mental and behavioral health care providers and facilities, in order to better integrate the delivery of mental and physical health care.

As you may know, Senator Sheldon Whitehouse (D-RI) and Senator Rob Portman (R-OH) introduced companion behavioral health information technology bills (S. 1517/S. 1685) in the 113th Congress, and Rep. Tim Murphy included a companion provision in his mental health reform bill, the Helping Families in Mental Health Crisis Act (H.R. 2646, as introduced). We recommend that the Committee adopt provisions similar to these bills in order to improve communication and collaboration within the health care delivery system for Medicare beneficiaries with chronic conditions.

Eliminate Barriers to Providing Important Telehealth Services.

We are pleased the Working Group has focused on telehealth issues and is considering removing some of the restrictions that limit its use by ACOs. To better address the critical need for mental and behavioral health care among Medicare beneficiaries, however, we recommend that the Committee consider modifying the requirements for reimbursement for telehealth services provided by psychologists whether or not the psychologist is an ACO participant.

As the Working Group has noted, CMS has established a number of criteria that must be met for the reimbursement of certain telehealth services provided to Medicare beneficiaries. The beneficiary must be located in a health professional shortage area or rural county and must be at an eligible originating site at the time services are delivered. Originating sites are generally clinical settings, such as a health care provider's office, hospital, rural health clinic, skilled nursing facility, or a federally qualified health center or community mental health center. CMS specifies which providers at the distant site are eligible to furnish services and receive payment, but there are no specific requirements for whether the distant site must be an office, hospital or clinic.

In addition, CMS requires that the interactive audio and video telecommunications system that is used must permit real-time communication between the practitioner at the distant site and the beneficiary at the originating site. Asynchronous or "store and forward" technology may only be used in certain federal demonstration projects.

While psychologists are able to provide a number of psychological services via telehealth to Medicare beneficiaries, the current requirements are still restrictive and impede the ability of a significant percentage of older Americans to access needed care. Specifically, the geographic restriction that a Medicare beneficiary be located in either a health professional shortage area or rural county to receive telehealth services should be removed, and the patient's home should be included in the list of eligible originating sites. Patient access is a concern for those in urban, suburban, and rural areas alike. In addition, many seniors may be home-bound and/or unable to travel to an eligible originating site for a variety of reasons (*e.g.*, multiple chronic health conditions, lack of transportation resources, or an inability to find an eligible site at which to receive a covered telehealth service).

CMS is taking steps forward by adding CCM services and care coordination management services to its list of approved telehealth services, and it appears that CMS has considered the possibility of waiving this requirement for ACOs, as mentioned in the recently published Final Rule on Medicare Shared Savings; Accountable Care Organizations.^{xi} It is CMS's position, however, that it lacks the "authority to implement many of these revisions under the current statute."^{xii} Therefore, we appreciate the Committee's interest in addressing the issue in order to allow changes in CMS's telehealth policies with respect to ACOs.

We recommend, however, that the changes mentioned above should be instituted for psychologists whether or not they are ACO participants. If the current requirements remain in place, a significant percentage of the Medicare population will continue to be unable to access needed mental and behavioral health care. In addition, with the rapid evolution in technology

and applications used to facilitate patient health visits and transmit health data, we recommend that the Committee encourage CMS to expand its definition of approved telehealth technology to allow for other modalities, such as asynchronous technology and telephone, that are compliant with relevant HIPAA and HITECH requirements and appropriate depending on the nature of the service involved. This would not only improve patient access given that some Medicare beneficiaries do not have videoconferencing resources, but would also provide clearer guidance to providers who are subject to HIPAA and HITECH requirements.

Consider Additional Evidence-Based Obesity Treatments.

As you know, obesity is a major national health concern that contributes to the risk of developing other costly, chronic health conditions, including diabetes, depression, and heart disease. Psychologists help fight obesity through behavioral interventions and counseling, and are experts in the diagnosis, assessment, and treatment of health risk behaviors.

We appreciate the Working Group's interest in a study to evaluate the utilization and impact of pharmaceutical therapies for obesity. We urge the Working Group, however, to explore a policy approach that facilitates patient access to the full range of evidence-based obesity treatments, including mental and behavioral, psychosocial, nutritional, pharmaceutical, and surgical interventions. Going forward, we hope the Working Group will consider additional, substantive obesity prevention and treatment measures, such as those provided in ***The Treat and Reduce Obesity Act (S. 1509)***.

The Treat and Reduce Obesity Act (S. 1509), sponsored by Senators Bill Cassidy (R-LA), Tom Carper (D-DE), Lisa Murkowski (R-AK), Martin Heinrich (D-NM), Charles Grassley (R-IA), and Chris Coons (D-DE) provides Medicare beneficiaries and their health care providers with meaningful tools to reduce obesity. The legislation would give CMS the authority to expand the provision of the Medicare benefit for Intensive Behavioral Therapy (IBT) for obesity beyond primary care physicians to additional types of health care providers, including clinical psychologists, non-primary care physicians, physician assistants, nurse practitioners, clinical nurse specialists, and registered dietitians or nutrition professionals. In addition, it would allow CMS to provide Medicare Part D coverage of FDA-approved prescription drugs for chronic weight management, as well as require the Secretary of Health and Human Services to report to Congress on steps taken to implement the Act, and to provide recommendations for better coordination of federal government efforts to reduce obesity.

Allow Psychologists to Provide Their Services to Beneficiaries in a One-Time Visit, Post Initial Diagnosis of Alzheimer's / Dementia or Other Serious Life Threatening Illness.

We applaud the Working Group's consideration of requiring that CMS implement a one-time payment to clinicians as reimbursement for the additional time needed to advise beneficiaries who receive a diagnosis of Alzheimer's/Dementia or other serious or life-threatening illness. This one-time visit code would allow the clinician to discuss with the patient the progression of

the disease, the treatment options, and the availability of other resources that could reduce the patient's health risks and promote self-management.

We welcome the Working Group's efforts in this area, and recommend that any directive to CMS on this point clearly indicate that psychologists must be among the list of health care providers permitted to bill any such new code. Given psychologists' professional focus, and their particular training and skill set, we believe it would clearly be appropriate to include them in the group of health care providers assisting and consulting with beneficiaries in this way, especially, but not only, in instances involving Alzheimer's/Dementia.

Adjust Medicare Payment Formula to End Erosion of Payments for Psychologists.

Medicare beneficiary access to needed mental health services is now jeopardized due to a steady and steep erosion in psychologist reimbursement rates. As a result of these substantial reductions, psychologists are leaving Medicare, reducing their patient loads, and refusing to take new patients. An APAPO member survey in 2013 revealed that 26% of responding psychologists who were previously Medicare providers had left the program, primarily due to low reimbursement rates. Half of those psychologists surveyed left since 2008. This means that nearly 5,200 psychologists across the country are no longer providing the mental, behavioral and substance use disorder services that Medicare beneficiaries need. Congress must act to reverse this trend, since as mentioned, psychologists are the principal providers of mental health services to Medicare beneficiaries.

In 2001, Medicare paid \$102 for a 45-minute psychotherapy session (the most common service). Today, the program pays just \$85.16 for the same service -- a drop of more than 30%, adjusted for inflation. Rates for other psychologist services have dropped by similar amounts. Most of the decline has occurred since 2007, the year CMS adopted a new methodology for calculating providers' practice expenses. Under the current formula, Medicare increasingly pays more for services associated with high practice expenses; *i.e.*, high-cost, technology-driven services furnished by providers with high overhead. This means that reimbursements to psychologists, who typically see relatively low overhead and equipment costs, are continually being squeezed in order to make room for increasingly higher payments to providers with higher practice expenses, despite the fact that the services psychologists provide are equal to or greater in complexity than the services furnished by many other types of providers.

We have met with CMS Deputy Administrator Sean Cavanaugh, most recently in October 2014, to discuss these concerns and ask the agency to address this continued erosion of psychologists' fees. A legislative solution, however, will likely be required. We have explored how the payment formula could be very slightly modified to accomplish this objective, and would be pleased to engage in a discussion of narrow legislative changes with you and your staff.

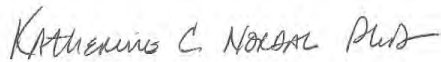
The continuing departure of psychologists from the Medicare program at a time when increasing numbers of Americans are becoming Medicare beneficiaries will severely hamper beneficiary access to effective mental and behavioral health care services. To enable psychologists to

remain in the program, and to allow a greater number to participate, Congress should adjust the payment formula to ensure fairer and more appropriate reimbursement.

Conclusion

We appreciate your consideration of our suggested policy reforms to more effectively and efficiently address the health care needs of Medicare beneficiaries with chronic conditions. We look forward to working with you and your colleagues on the Working Group this Congress. Please call or email Doug Walter, J.D., Associate Executive Director, in the APAPO Government Relations Office at (202) 336-5889 or dwalter@apa.org should you have any questions regarding our responses or wish for further assistance.

Sincerely,



Katherine C. Nordal, Ph.D.
Executive Director for Professional Practice

ⁱ Medicare Beneficiary Prevalence for Chronic Conditions for 2013, CMS Chronic Condition Data Warehouse (CCW). Online at https://www.ccwdata.org/cs/groups/public/documents/document/ccw_website_table_b2.pdf.

ⁱⁱ National Suicide Statistics at a Glance - Trends in Suicide Rates Among Both Sexes, by Age Group, United States, 1991-2009. Centers for Disease Control and Prevention. Online at <http://www.cdc.gov/violenceprevention/suicide/statistics/trends02.html>.

ⁱⁱⁱ Substance Abuse and Mental Health Services Administration. Projections of National Expenditures for Treatment of Mental and Substance Use Disorders, 2010–2020. HHS Publication No. SMA-14-4883. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2014.

^{iv} The Synthesis Project, New Insights from Research Results, Policy Brief No. 21, February 2011; NHW National Healthy Worksite, <http://www.cdc.gov>.

^v Unutzer, J. et al. (2009). Healthcare costs associated with depression in medically ill fee-for-service Medicare participants. *Journal of the American Geriatrics Society*, 57, 506-510.

^{vi} Kathol, R. G., Butler, M., McAlpine, D. D., & Kane, R. L. (2010). Barriers to physical and mental condition integrated service delivery. *Psychosomatic Medicine*, 72(6), 511-518.

^{vii} Olfson, M., Kroenke, K., Wang, S., & Blanco, C. (2014). Trends in office-based mental health care provided by psychiatrists and primary care physicians. *The Journal of clinical psychiatry*, 75(3), 247-253.

^{viii} Mitchell, A. J., Vaze, A., & Rao, S. (2009). Clinical diagnosis of depression in primary care: a meta-analysis. *The Lancet*, 374(9690), 609-619.

^{ix} Arnold, M. (2008). Polypharmacy and older adults: A role for psychology and psychologists. *Professional Psychology: Research and Practice*, 39, 283-289.

^x Gum, A. M., Arean, P. A., Hunkeler, E., Tang, L., Katon, W., Hitchcock, P., Steffens, D.C., Dickens, J., & Unutzer, J. (2006). Depression treatment preferences in older primary care patients. *The Gerontologist*, 46, 14-22.

^{xi} 80 Fed. Reg., 32695 (2015)

^{xii} 79 Fed. Reg., 67602 (2014)