Date: June 1, 2011

To: Kathleen Sebelius
Secretary, Department of Health & Human Services

Donald Berwick
Administrator, Centers for Medicare & Medicaid Services

From: Greg T. Greenwood
President, Human Capital Specialists, Inc.

Re: CMS-1345-P; Failure to Integrate Behavioral Health into the Medicare Shared Savings Program

Dear Secretary Sebelius and Dr. Berwick:

As President of Human Capital Specialists ("HC*Specialists*"), I thank you for the opportunity to provide comments to the proposed rules of the Medicare Shared Savings Program ("MSSP"). Combining expertise in human behavior with comprehensive experience in healthcare operations, HC*Specialists* collaborates with local and national health plans, insurers, providers and public health leaders to promote evidence-based best practices, optimize healthcare resources and improve patient outcomes. Previously, I served as a consultant to the National Advisory Mental Health Council of the National Institute of Health in issuing *Parity in Financing Mental Health Services: Managed Care Effects on Cost, Access & Quality*. HC*Specialists* is filing these comments in response to the Centers for Medicare & Medicaid Services' ("the Agency") issuance of proposed rules for the MSSP in the *Federal Register* on April 7, 2011. Our comments below include specific recommendations on particular provisions of the proposed regulations.

Summary Statement

After careful review of the proposed Accountable Care Organization ("ACO") regulations, HC*Specialists* is deeply concerned over the: (a) glaring lack of reference to behavioral health services, those pertaining to mental health and substance abuse concerns, (b) failure to recognize the critical role that behavioral health services and providers play in the larger health system and (c) disregard for the considerable potential of evidence-based behavioral health services for promoting the Affordable Care Act's goal of a more functionally-integrated, patient-centered, outcomes-oriented and cost-effective healthcare system.

From a policy perspective, HC*Specialists* regards the proposed ACO regulations as directly in conflict with national mental health and substance abuse parity legislation and contrary to other advancements in federally sponsored healthcare programming that promote integration of behavioral health services into primary medical care systems. From a quality of care perspective, failure to imbed a full range of behavioral health services into the basic structure and function of ACOs risks inadequate care – not just for the millions of beneficiaries with diagnosed mental health or substance abuse disorders, but for the even larger population that is impacted by unrecognized behavioral factors that contribute to their total health and limit their responsiveness to medical treatment. From a cost-effectiveness perspective, failure to include evidence-based, patient-centered behavioral health services as a fundamental element of ACOs will result in a major missed opportunity to capitalize upon integration of behavioral and primary

medical services. There is indisputable research evidence that behavioral health services are a key strategy for reducing medical service utilization and costs, while improving clinical effectiveness, patient satisfaction and meaningful outcomes.

HC*Specialists'* concerns are amplified by the fact that the influence of the MSSP on the nation's health system will extend beyond public delivery systems of treatment services. Due largely to the capitalization required for creation of an ACO, hospitals and physician groups are partnering with insurers to form entities to participate in the MSSP. These partnerships will cross over into commercial plans, and that will spread the clinical model advanced by the proposed regulations beyond Medicare. Unless the proposed regulations are modified (as we have recommended below), the Agency could perpetuate unintended and negative consequences throughout Medicare and the entire healthcare system, including inadequate care, limited treatment effectiveness and missed savings opportunities.

Evidence to Support HC*Specialists*' Position

In the following paragraphs, HC*Specialists* explains the ways in which the proposed ACO regulations conflict with current federal and state legislation and advancements in sponsored healthcare programming.

Conflict 1:
Three major goals of the Affordable Care Act are compromised by the Agency's failure to integrate behavioral health into ACOs.

I. Sharing Evidence of Best Practices

To control the costs of American healthcare, Congress sought to promote evidence-based treatment practices through various provisions of the Affordable Care Act. The law requires the Agency, as well as other sections of the Department of Health & Human Services, to use research—especially comparative clinical-effectiveness studies—and measurements to improve the delivery of healthcare services.

For example, under the Affordable Care Act, the Agency for Healthcare Research and Quality ("AHRQ") is tasked with disseminating the work of the new Patient-Centered Outcomes Research Institute. The institute will "assist patients, clinicians, purchasers, and policy-makers in making informed health decisions" through comparative clinical-effectiveness research.[1] AHRQ's Office of Communication and Knowledge Transfer will then "broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute."[2]

Congress also established "National Centers of Excellence for Depression" to share research, release treatment standards, devise clinical guidelines, and "establish and maintain a national, publicly available database to improve prevention programs, evidence-based interventions, and disease management programs for depressive disorders."[3]

With the clinical design presented by the interim regulations, ACOs will be unprepared to implement guidelines, standards and interventions pertaining to behavioral health.

[1] 42 USC § 1320e.

[2] 42 U.S.C. § 299b-37.

[3] 42 U.S.C. § 290bb-33.

II. Coordination of Care Across Specialty Practices

The MSSP is an example of the Affordable Care Act's effort to promote the "medical home" model of service delivery. In addition to encouraging coordination of care across treatment settings, this framework encourages practitioners of healthcare specialties to collaborate and achieve improved patient outcomes.

Within the Agency, Congress established the Center for Medicare and Medicaid Innovation to promote medical homes and other service-delivery models that "improve the coordination, quality, and efficiency of health care services."[4] Elsewhere in the reform law, Congress included a section for "Establishing Community Health Teams to Support the Patient-Centered Medical Home", with the requirement that these health teams "implement interdisciplinary, interprofessional care plans."[5]

Separately, the legislation provides a Medicaid program to designate medical homes for beneficiaries with multiple chronic conditions, including a "serious and persistent mental health condition."[6] Under that part of the law, the term "coordination" describes an interface with behavioral health expertise.[7]

Although these new programs will share the goal of care coordination with the MSSP, the Agency is not poised to equip ACOs with similar access to behavioral health expertise.

III. Reward Quality, Not Quantity, of Services

The MSSP is perhaps the best example of Congress' effort to alter the Agency's programs by creating incentives for the streamlining of treatment services by providers.

Congress intended for ACOs to "promote[] accountability for a patient population" and deliver services by "redesigned care processes for high quality and efficient service delivery."[8] The Affordable Care Act gives ACOs the opportunity to share in the savings achieved by such efficiency, while making them responsible for devising processes to promote evidence-based medicine, patient engagement, and coordination of care.[9]

As federal health systems have discovered – both in practice and in study – improved outcomes and efficiencies result from the integration of behavioral health treatment with primary care services. As currently proposed, the MSSP will not benefit from these experiences.

Conflict 2:
The Agency's neglect of behavioral health is contrary to recent national policy.

I. Federal and State Legislation Promoting Behavioral Healthcare

[4] 42 U.S.C. § 1315a.

[5] 42 U.S.C. § 256a-1(c)(4).

[6] 42 U.S.C. § 1396w-4(h)(1).

[7] 42 U.S.C. § 1396w-4(e) ["Coordination.--A State shall consult and coordinate, as appropriate, with the Substance Abuse and Mental Health Services Administration in addressing issues regarding the prevention and treatment of mental illness and substance abuse among eligible individuals with chronic conditions."].

[8] 42 U.S.C. § 1899(a)(1).

[9] 42 U.S.C. § 1899(b)(2)(G).

With the Mental Health Parity Act of 1996, Congress equalized annual and lifetime insurance limits on mental health benefits to match limits for medical benefits. At that time, a dozen states had also adopted mental health parity provisions of their insurance codes.[10] The National Institute of Health reported to Congress that states promoting equal access to behavioral health treatments in conjunction with appropriate case management experienced no additional healthcare costs.[11] So Congress passed further parity legislation – the Mental Health Parity and Addiction Equity Act of 2008 – requiring insurers and group health plans that offer coverage of behavioral health treatment to make those benefits comparable to medical benefits.[12]

In 2008, Congress also brought behavioral health parity to the Agency: equalizing Medicare reimbursements for behavioral health practitioners under the Medicare Improvements for Patients and Providers Act of 2008.[13]

In 2014, when insurance exchanges open to newly-insured Americans, participating health plans will abide by mental health parity, and all coverage acquired via an exchange will include behavioral health benefits.[14] Regardless of the Secretary's definition of minimum standards for these benefits, a majority of states already require coverage for serious mental illnesses[15] and nearly as many mandate offers of substance abuse coverage.[16]

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[10] See, National Advisory Mental Health Council *Parity in Financing Mental Health Services* (National Institute of Mental Health Archive, 1998) at 54 [listing states that had enacted mental health parity laws by 1997 as: Arizona, Arkansas, Colorado, Connecticut, Indiana, Maine, Maryland, Minnesota, Missouri, New Hampshire, North Carolina, Rhode Island, South Carolina, Texas and Vermont]. Now, at least forty states have mental health parity statutes: Alabama (§ 27-54-4(b)), Alaska (§ 21.54.151), Arizona (§ 20-2322), Arkansas (§§ 23-99-501 to 23-99-12), California (Health & Safety § 1374.72), Colorado (§ 10-16-104), Connecticut (§ 38a-476a), Delaware (Ins. § 3343), Georgia (§ 33-29-24.1), Hawaii (§ 431M-5), Idaho (for state employees at § 67-5761A), Illinois (215 § 5/370c), Indiana (§§ 27-13-7-14.8, 27-8-5-15.6), Kansas (§ 40-2,105a), Kentucky (§304.17-318), Maine (24-A § 2749), Maryland (Ins. § 15-802), Massachusetts (Ch. 175, § 47B), Minnesota (62Q.47), Missouri (§ 376.811), Montana (§33-22-703), Nebraska (§ 44-793), New Hampshire (§ 415:18-a), New Mexico (§§ 59A-23E-18), New York (Ins. § 3221(1)(5)(A)), North Carolina (§ 58-3-220**)**, North Dakota (§26.1-36-08), Ohio (§§ 3923:29, 3923:281, 3923:282), Oklahoma (§ 6060.11) , Oregon (§ 743A.168), Rhode Island (Ch. 27-38.2), South Carolina (§ 38-71-290), South Dakota (§ 58-17-98), Tennessee (§ 56-7-2360 [mental health], § 56-7-2602 [substance abuse]), Texas (Ins. § 1355), Vermont (8 § 4089b), Utah (§ 31A-22-625), Virginia (38.2 § 3412.1:01 [mental health only]), West Virginia (§ 33-15-4a), and Wisconsin (§ 632.89).

[11] National Advisory Mental Health Council *Parity in Financing Mental Health Services* (National Institute of Mental Health Archive, 1998)

[12] 29 U.S.C. § 1185a; 29 C.F.R. § 2590.712.

[13] 42 U.S.C. § 13951(c).

[14] 42 U.S.C. § 18031(j); 42 U.S.C. § 18022(b)(1)(E).

[15] Insurance coverage for the treatment of mental illness is required by Alabama (27-54-4(a)), Arkansas (§ 23-86-113), California (Ins. § 10125), Colorado (§ 10-16-104), Connecticut (§ 38a-488a), Delaware (Ins. § 3578), Florida (§ 627.668), Georgia (§ 33-24-28.1), Hawaii (§ 431M-4(c)), Illinois (215 § 5/370c), Iowa (§ 514C.22), Kansas (§ 40-2,105), Kentucky (§304.17-318), Louisiana (R.S. 22:1043), Maine (24-A, §§2749, 2843, 4234-A**)**, Massachusetts (Ch. 175, § 47B), Missouri (§§ 376.814, 376.1550), Montana (§33-22-703), Nevada (§§ 689A.0455, 689C.169), New Hampshire (§ 417-E:1), New Jersey (§§ 17:48-6v, 17:48A-7u, 17:48E-35.20, 17B:26-2.1s, 17B:27-46.1v), North Carolina (§ 58-3-220), Ohio (§ 3923:282), Oklahoma (§ 6060.11), Oregon (§ 743A.168), Rhode Island (Ch. 27-38.2), South Carolina (§ 38-71-290), South Dakota (§ 58-17-98), Tennessee (§ 56-7-2601), Texas (Ins. § 1355), Utah (§ 31A-22-625 [mandating offer of coverage]), Vermont (8 § 4089b), Virginia (38.2 § 3412.1), Washington (§ 48.21.241 [commercial insurance] and § 48.41.220 [coverage by state insurance pool]), West Virginia (§ 33-16-3a) Wisconsin (§ 632.89), and Wyoming (§§ 26-22-102, 26-22-106).

[16] Insurance coverage for the treatment of substance abuse is required by Arkansas (§ 23-79-139), Colorado (§ 10-16-104[mandating offer of coverage for alcoholism]), Delaware (Ins. § 3343(b)), Florida (§ 627.669), Hawaii (§ 431M-4(b)), Kansas (§ 40-2,105), Louisiana (R.S. 22:1025), Maine (24-A, §2842), Maryland (§ 15-802), Mississippi (§ 83-9-27), Missouri (§ 376.811), Montana (§33-22-703), Nevada (§§ 689A.046, 689C.166), New Jersey (§§ 17:48-6a, 17:48A-7a, 17:48E-34, 17B:26-2.1), New Mexico (§§ 59A-23-6; 59A-47-35), North Dakota (§26.1-36-08), Ohio (§ 3923:29) **,** Oregon (§ 743A.168), Tennessee (§ 56-7-2601), Texas (Ins. § 1368), Utah (§ 31A-22-625 [mandating offer of coverage]), Vermont (8 § 4089b), Virginia (38.2 § 3412.1), and Wisconsin (§ 632.89).

II. Promotion of Behavioral Health Integration by Federal Programs

Beneficiaries of another federal health system have recently enjoyed greater access to behavioral health treatment services. The Veterans Administration ("VA") has implemented behavioral health integration in its busiest facilities and clinics. VA facilities serving more than ten thousand veterans per year "must have integrated mental health services that operate in their primary care clinics on a full-time basis." [17]

Prior to the patient-centered outcomes research commissioned under the Affordable Care Act, AHRQ has already issued an assessment of the integration of behavioral health in primary care settings. That report of current evidence stated "In general, integrated care achieved positive outcomes", but cautioned "Efforts to implement integrated care will have to contend with the financial barriers posed by fee-for-service payment. Many of the costs involved are not regularly covered by a payment system based on specific in-person encounters."[18]

The Medicare Shared Savings Program is an opportunity to promote behavioral health integration and incentivize solutions to those barriers posed by a strict fee-for-service model.

HC*Specialists*' Recommendations to the Proposed Regulations for the Medicare Shared Savings Program

In the following paragraphs, HC*Specialists* provides specific recommendations. *We have included text modifications, as well as our rationale for the suggested changes.*

Recommendation 1: The definition of "ACO Professional" should include clinical psychologists.

Recommended Change:

Revise § 425.4 to include clinical psychologists as ACO Professionals.

HC*Specialists* recommends replacing the definition of ACO Professional in proposed § 425.4 with (recommended changes are underlined):

> ACO professional means an ACO provider/supplier who is either of the following:
> (1) A doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he or she performs such function or action, including an osteopathic practitioner within the scope of his or her practice as defined by State law.
> (2) A practitioner who is one of the following:
> (i) A clinical psychologist (as defined at § 410.71(d)).
> (ii) A physician assistant (as defined at §410.74(a)(2)).
> (iii) A nurse practitioner (as defined at §410.75(b)).
> (iv) A clinical nurse specialist (as defined at §410.76(b)).

Reasoning Behind HCSpecialists' Recommended Change

As proposed, § 425.4 limits the definition of "ACO Professionals" to doctors of medicine, physician assistants, nurse practitioners, and clinical nurse specialists. This is based on a

[17] Veterans Health Administration Handbook, 1160.01, Uniform Mental Health Services, ¶ 21.

[18] *Integration of Mental Health/Substance Abuse and Primary Care*, AHRQ Publication No. 09-E003 at 5 (October 2008).

provision of the enabling legislation, which defines ACO professionals by reference to the Social Security Act.[19] However, the Affordable Care Act grants the Secretary discretion to expand the list of practitioners who may participate in management of ACOs.[20]

Federal law recognizes that physicians are not exclusive supervisors of care, and that clinical supervision by a psychologist is sometimes more appropriate. In the Social Security Act, Congress declared that some beneficiaries require care that is supervised by a clinical psychologist, rather than a physician.[21] Similarly, in Federally Qualified Health Centers, physicians provide medical directions "except for services furnished by a clinical psychologist."[22]

The Agency already includes clinical psychologists alongside physician assistants, nurse practitioners, and clinical nurse specialists for the purposes of Medicare reimbursement.[23] The Social Security Act includes treatment provided by clinical psychologists in definitions of "medical and other health services" and "rural health clinic services".[24]

HC*Specialists*' recommended change also reflects state law, as clinical psychologists are recognized by almost all states through certification by the National Register of Health Service Providers in Psychology.[25]

The expertise of supervising psychologists is critical to the mission of ACOs. Between 50 and 70% of a physician's normal caseload consists of patients whose medical ailments are significantly related to psychological factors.[26] A national study of hospitals found 12% of emergency department visits were related to mental health and substance abuse, and 40% of these visits resulted in hospital admission.[27]

Clinical supervision by psychologists is also a vital means for ACOs to devise more efficient practices and achieve savings. Over two-thirds of patients with depression in primary care settings first present with somatic symptoms, resulting in unnecessary medical tests and delayed treatment.[28] This occurs, in part, because physical discomfort – headaches, sleep disturbance, gastrointestinal symptoms – resulting from psychological distress is a common reason for seeking medical care, even without a diagnosable psychiatric disorder.[29] A 20-year

[19] 42 USC § 1899(h) [referencing 42 USC § 1861(r)(1) and 42 USC § 1842(b)(18)(C)(i)].

[20] 42 USC § 1899(b)(1)(E).

[21] 42 USC § 1861(e)(4) [defining "Hospitals" and requiring that "every patient . . . must be under the care of a physician except that a patient receiving qualified psychologist services . . . may be under the care of a clinical psychologist"].

[22] 42 C.F.R. § 491.8(a)(3).

[23] 42 USC § 1842(b)(18)(C).

[24] 42 USC § 1861(s)(2)(H); 42 U.S. § 1861(aa)(1).

[25] Certification by the National Register of Health Service Providers in Psychology is recognized by Arizona, Arkansas, California, Delaware, Hawaii, Idaho, Indiana, Iowa, Kentucky, Maine, Massachusetts, Minnesota, Missouri, Montana, Nebraska, Nevada, New Mexico, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and Wisconsin. The certification defines a health service provider in psychology as "a licensed/certified psychologist, at the independent practice level in his/her state, province, territory, or country, who is trained and experienced in the delivery of prevention, consultation, assessment, and treatment." (*See*, www.nationalregister.org)

[26] VandenBos, G.R. & DeLeon, P.H. (1988). The use of psychotherapy to improve physical health. *Psychotherapy;* 25, 335-343.

[27] Owens, P., Mutter, R.L. & Stocks, C. (2010). Mental health and substance abuse-related emergency department visits among adults, 2007. Rockville, MD: Agency for Healthcare Research and Quality. http://www.hcup-us.ahrq.gov/reports/statbriefs/sb92.pdf.

[28] Kirmayer, L.J., Robbins, J.M., Dworkind, M., et al. (1993). Somatization and the recognition of depression and anxiety in primary care. *American Journal of Psychiatry*; 150: 734-741.

[29] Sobel, D.S. (2000). The cost-effectiveness of mind-body medicine interventions. *Prog Brain Res;* 122: 393-412.

study by Kaiser Permanente found that 60% of all medical visits were by the "worried well", patients with no diagnosable disorder at all.[30]

Recommendation 2:
Patient-centeredness criteria should include consideration of behavioral health.

Recommended Changes:

a. Revise § 425.5(d)(15)(ii)(B)(3) to redefine "health" as not just a result of physical well-being, but as a function of both medical and psychosocial factors.

HC*Specialists* recommends replacing proposed § 425.5(d)(15)(ii)(B)(3) with (recommended changes are underlined):

> (3) A process for evaluating the comprehensive medical and psychosocial health needs of the ACO's assigned population, including consideration of diversity in its patient populations, and a plan to address the needs of its population

b. Revise § 425.5(d)(15)(ii)(B)(4) to emphasize the critical relationship between medical and psychosocial factors in determining overall health.

HC*Specialists* recommends replacing proposed § 425.5(d)(15)(ii)(B)(4)(ii) with (recommended changes are underlined):

> (ii) The plan must be tailored to the beneficiary's medical and psychosocial needs, account for beneficiary preferences and values, and identify community and other resources to support the beneficiary in following the plan

c. Revise § 425.5(d)(15)(ii)(B)(6) to account for psychological factors in a person's ability to comprehend information and to replace the term "evidence-based medicine", because not all treatment information or procedures are strictly "medical" in nature – many are behavioral or social in their basic form and do not involve any pharmaceuticals, surgery or other traditional medical procedures.

HC*Specialists* recommends replacing proposed § 425.5(d)(15)(ii)(B)(6) with (recommended changes are underlined):

> (6) A process in place for communicating evidence-based clinical information to beneficiaries in a way that is understandable to them, given individual differences in education, culture and cognitive/emotional functioning

d. Revise § 425.5(d)(15)(ii)(B)(7) to emphasize the importance of psychological factors not just in understanding information, but being able to use it.

HC*Specialists* recommends replacing proposed § 425.5(d)(15)(ii)(B)(7) with (recommended changes are underlined):

[30] Cummings, N.A. & VandenBos, G.R. (1981). The twenty years Kaiser-Permanente experience with psychotherapy and medical utilization: implication for national health policy and national health insurance. *Health Policy Quarterly*, 1:159-175.

(7) A process in place for beneficiary engagement and shared decision-making that takes into account the beneficiaries' unique needs, preferences, values, and priorities and is tailored to individual capacities for understanding, judgment, motivation and using information in their best interest

Reasoning Behind HCSpecialists' Recommended Changes:

Health status is determined by the combined effect of biological, psychological and social factors. Effective treatment must be based upon a full understanding of the role that these three types of factors play, not only in the development of medical disorders and presentations, but in a person's compliance with and response to medical intervention.

For an ACO to identify and be responsive to a population's needs, it must extend its focus beyond global "health" needs and cultural influences of targeted populations (as the proposed regulations would require), and direct efforts toward implementation of tailored treatment plans that are based on a full understanding of the medical, psychological and social factors that determine health needs and treatment responsiveness for each individual beneficiary.

The proposed rules' process for evaluating "the health needs" of the ACO's assigned population does not also account for behavioral health needs. Individuals with chronic medical diseases demonstrate a greater risk for co-occurring behavioral health conditions. Studies estimate that patients with chronic physical health illnesses are two to three times more likely to suffer from depression than healthy individuals.[31] Major depression has been diagnosed in 45% of individuals hospitalized after myocardial infarction,[32] with significantly higher death rates for depressed patients.[33] Depression or depressive symptoms are also predictive of experiencing a stroke within 10 years of diagnosis.[34]

Individuals vary in their capacities for comprehending clinical information, complying with treatment recommendations and for making independent choices in their own best interests. Interpersonal and social environments can sometimes thwart even the best planned evidence-based interventions. Therefore, effective treatment planning must include routine evaluation of individual psychological functioning and social context, while effective treatment must address the full range of variables that can impact treatment outcomes.

Recommendation 3:
Expand the requirement of depression screenings to include outcome measurement and monitoring.

Recommended Change:

Quality Reporting and Performance Requirement #34 (page 174, Table 1) is the only proposed measurement concerning behavioral health. The proposed measure is derived from Physician Quality Reporting System #134 and National Quality Forum #418.

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[31] National Institute for Health and Clinical Excellence. (2009). Depression in Adults with a Chronic Physical Health Problem: Treatment and Management. NICE Clinical Guideline 91.

[32] Fauerbach, J., Bush, D.E., Thombs, B.D., McCann, U.D., et al. (2005). Depression following myocardial infarction: A prospective relationship with ongoing health and function. *Psychosomatics,* 46(4), 355.

[33] Frasure-Smith, N., Lesperance, F., & Talajic, M. (1993). Depression following myocardial infarction: Impact on 6-month survival. *JAMA, 270,* 1819-1196.

[34] Ohira, T., Iso, H., Satoh, S., Sankai, T., Tanigawa, T., Ogawa, Y., et al. (2001). Prospective study of depressive symptoms and risk of stroke among Japanese. *Stroke*; 32: 903–908.

HC*Specialists* recommends enhancing proposed Quality Reporting and Performance Requirement #34, by incorporating elements of National Quality Forum #17 (recommended changes are underlined):

> Percentage of patients aged 18 years and older screened for clinical depression using the Patient Health Questionnaire (PHQ-9) tool and follow up plan documented for screening results with a PHQ-9 score > 9, with monitoring and re-assessment until remission is achieved (PHQ-9 score < 5).

Reasoning Behind HCSpecialists' Recommended Change:

The measurement domains proposed by § 425.10 derive from examples provided by Congress, including: clinical processes and outcomes, patient experience of care, utilization rates, hospital discharge planning and post-discharge follow-up, use of electronic health records, and other performance standards.[35] Proposed Performance Requirement #34 does not match these examples because it offers no measure of the frequency with which beneficiaries might actually receive treatment for depression, nor any information about the outcome of such treatment. Without the use of outcome measures, an assessment of treatment effectiveness—in terms that matter to both patients and all other stakeholders—will be impossible and calculation of the monetary "value" of ACOs' services will be limited.

HC*Specialists*' recommended change is similar to the depression screening guideline established in 2009 by the U.S. Preventive Services Task Force.[36] The recommended change promotes early identification of the most prevalent (and underdiagnosed) behavioral health disorder – depression. The recommended change also expands the focus of the measure beyond mere screening because the PHQ-9 is a valid, easy-to-use tool for tracking outcomes. Finally, the change recommends specific cut-off scores for initiating treatment and evaluating progress.

Overall, the Agency's proposed quality performance indicators include measures for a number of high-risk medical populations and the frail elderly, but do not identify one other important high-risk group: persons with serious and chronic behavioral conditions. Recent evidence shows that persons with severe and persistent mental illness (who are also highly prone to present with coexisting substance abuse concerns) are much more apt to develop a myriad of refractory medical conditions that are not only difficult and expensive to treat (i.e., obesity, metabolic syndrome/diabetes, hypertension, cardiovascular disease, and chronic obstructive pulmonary disease), but also reduce average lifespan.[37] HC*Specialists*' recommendation mitigates this deficiency in the proposed measures—without adding to the volume of measures—by promoting identification of depression, the most prevalent and underdiagnosed behavioral health disorder, and effective treatment of this condition.

In recommending this change, HC*Specialists* considered The Joint Commission's ("TJC") recent implementation of a new framework for issuing accountability measures. TJC's measures are reported by hospitals to the Agency, and TJC's new criteria are intended to influence the

[35] 42 U.S.C. § 1899(b)(3).

[36] See, http://www.uspreventiveservicestaskforce.org/uspstf09/adultdepression/addeprsum.htm

[37] Miller, B. J., Paschall, C. B. & Svendsen, D. P. (2006). Mortality and medical comorbidity among patients with serious mental illness. *Psychiatric Services,* 57:10, 1482-1487.

delivery of care, rather than merely collect data.[38] As proposed, Performance Requirement #34 would not meet TJC's new criteria, the first of which is that the process addressed by a measure should lead to improved clinical outcomes. The standard in the proposed rule will provide the Agency with a false sense of ACOs' accomplishment in the area of behavioral health.

To keep Medicare from falling behind private delivery systems, Performance Requirement #34 must go beyond a mere screening requirement. Recent regulations implementing the Affordable Care Act's medical loss ratio requirement reject "clinical data collection without any subsequent data analysis" as a quality improvement activity.[39] If the Medicare Shared Savings Program intends to reward quality, it should require outcomes.

* * * *

Thank you for the opportunity to comment on the proposed regulations governing the Medicare Shared Savings Program and for considering our recommendations. On behalf of HC*Specialists*, I look forward to working on the Agency's behalf to implement the Affordable Care Act's ACO provisions.

If you have any questions, please contact me, David K. Ries, Esq., Larry A. Cesare, Psy.D., or Kristina L. Greenwood, Ph.D. at (619) 696-9655.

Sincerely,

s/ Greg T. Greenwood

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[38] Chassin, M.R., Loeb, J.M., Schmaltz, S.P., & Wachter, R.M. (2010). Accountability measures--using measurement to promote quality improvement. *N Engl J Med*, 363(7): 683-688.

[39] 45 CFR § 158.150(c).