

June 1, 2020

Ms. Seema Verma, MPH Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Attention: CMS-1744-IFC PO Box 8016 Baltimore, MD 21244-8010 120 South Riverside Plaza Suite 2190 Chicago, Illinois 60606-6995 800.877.1600

1120 Connecticut Avenue NW Suite 460 Washington, D.C. 20036

Re: File code CMS-1744-IFC Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Dear Administrator Verma:

The Academy of Nutrition and Dietetics (the "Academy") appreciates the opportunity to provide input on the Centers for Medicare and Medicaid Services' (CMS's) Interim Final Rule: Policy and Regulatory Revision in Response to the COVID-19 Public Health Emergency.

The Academy represents over 107,000 registered dietitian nutritionists (RDNs)¹, nutrition and dietetic technicians, registered (NDTRs), and advanced-degree nutritionists. The Academy is the largest association of nutrition and dietetics practitioners in the world committed to accelerating improvements in global health and well-being through food and nutrition. RDNs independently provide professional services such as medical nutrition therapy (MNT)² under Medicare Part B and are recognized as Eligible Clinicians (ECs) and Qualified APM Participants (QPs) in Medicare's Quality Payment Program. RDNs provide high quality, evidence-based care to patients and deliver substantial cost-savings to the health care system.

The Academy supports continued efforts to deliver safe and effective nutrition care to Medicare beneficiaries by maximizing capabilities within existing federal statutes that facilitate telehealth and streamline the provision of care without expanding covered services or increasing costs. We commend CMS for their rapid response in offering flexibilities to accommodate the needs of patients and providers during this public health emergency (PHE) in alignment with input received from all stakeholders.

The Academy offers specific comments on the following items in the final rule:

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section A)

¹ The Academy has approved the optional use of the credential "registered dietitian nutritionist (RDN)" by "registered dietitians (RDs)" to more accurately convey who they are and what they do as the nation's food and nutrition experts. The RD and RDN credentials have identical meanings and legal trademark definitions.

² Medical nutrition therapy (MNT) is an evidence-based application of the Nutrition Care Process. The provision of MNT (to a patient/client) may include one or more of the following: nutrition assessment/reassessment, nutrition diagnosis, nutrition intervention and nutrition monitoring and evaluation that typically results in the prevention, delay or management of diseases and/or conditions. Academy of Nutrition and Dietetics' Definition of Terms list updated May 2020. Accessed May 22, 2020.

- 2. Telehealth Modalities and Cost-sharing (Section C)
- 3. Communication Technology-Based Services (CTBS) (Section D)
- 4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Section L)
- 5. Innovation Center Models (Section Q)
- 6. Telephone Evaluation and Management (E/M) Services (Section S)
- 7. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic (Section U)
- 8. Merit-based Incentive Payment System Updates (Section BB)

1. Payment for Medicare Telehealth Services Under Section 1834(m) of the Act (Section A)

The Academy supports CMS' decision to pay Medicare providers for Medicare visits furnished by telehealth at the same rate as when provided in-person. We believe this decision acknowledges not only the resources to support the telehealth visit but also recognizes the time spent by qualified health care professionals (both physician and non-physician providers) using such technologies for assessment, treatment, evaluation and monitoring functions needs. This will enable beneficiaries continued access to reliable health and medical services which in turn, we believe will support adherence to treatment plans for Medicare beneficiaries, particularly those with diabetes, chronic kidney disease, and renal transplants.

The Academy requests CMS add HCPCS code G0271 to the list of approved Medicare telehealth services to achieve alignment across the family of codes. We believe that the addition of HCPCS G0271 falls under Category 1 in accordance with section 1834(m)(4)(F)(ii) of the Social Security Act which outlines Category 1 services are "similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services... we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter...We also look for similarities in the telecommunications system used to deliver the service."

The current list of Medicare telehealth services³ includes:

- CPT code 97802 Medical nutrition therapy, initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97803 Medical nutrition therapy, re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes
- CPT code 97804 Medical nutrition therapy, group (two or more individuals), each 30 minutes
- HCPCS code G0270 Medical nutrition therapy, reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen, individual, face-to-face with the patient, each 15 minutes

³ CMS, Telehealth Services. https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes. Accessed May 22, 2020.

HCPCS code G0271 is analogous to CPT Code 97804 for group medical nutrition therapy reassessment and subsequent intervention(s) for a change in diagnosis, medical condition or treatment regimen. Therefore, we believe it meets Category 1 criteria for inclusion in the list of approved Medicare telehealth services.

2. Telehealth Modalities and Cost-sharing (Section C)

CMS revised on an interim basis for the duration of the PHE for the COVID-19 pandemic measures that allow use of any device that could otherwise meet the interactive requirements for Medicare telehealth, meaning that multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner may be utilized⁴. The Academy supports CMS' belief that leveraging the use of readily available technology is of critical importance during this time of social distancing and safer at home mandates.

3. Communication Technology-Based Services (CTBS) (Section D)

We commend CMS on the action taken in Medicare CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule which finalized separate payment for HCPCS Codes G2061-3 (online assessment and management services). RDNs frequently receive inquiries from patients through a variety of communication technologies about physiological data (e.g., blood glucose self-monitoring results, blood pressure, weight, and nutrition-related serum values such as potassium), medications, physical activity, adverse symptoms and/or food intake related to their nutrition care plan. Information gathered through either phone or online communication platforms allows RDNs to make decisions about whether an MNT encounter may be necessary. A virtual check-in offers the opportunity to make simple adjustments in a nutrition care plan that helps to avoid higher cost encounters with the health care system (e.g., hospitalizations, emergency department or urgent care center visits) and/or additional long distance trips to health care professionals for patients located in rural areas.

We ask that CMS **specifically include all Medicare providers in guidance for use of communication technology-based services.** In guidance⁵ and FAQs⁶ released by CMS on telehealth waivers, registered dietitians and nutrition professionals are not specifically listed as Medicare providers for use of G2061-3. We believe the agency's intent when listing eligible Medicare providers was to highlight those providers who are not eligible to provide telehealth services but can provide these communication technology-based services. However, stakeholders (including administrators and billing staff) are interpreting the information published by CMS quite literally and are mistakenly believing that they cannot bill for these services when provided by a registered dietitian. A comprehensive list of eligible providers for these codes would provide much-needed clarity.

⁴ CMS-1744-IFC, Section C Telehealth modalities and cost sharing.

⁵ CMS-1744-IFC, Section D: Communication Technology-Based Services.

⁶ COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing. https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf . Accessed April 28, 2020

4. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (Section L)

The Academy supports CMS's decision to expand services that can be included in the payment for HCPCS code G0071 to include on-line evaluation and management services (CPT codes 99421-3) and to make such services available to both new and established RHC and FQHC patients. For similar reasons, the Academy urges CMS to also include HCPCS codes G2061-3 in the payment for G0071. Registered dietitian nutritionists and other non-physician RHC and FQHC staff (e.g., social workers) provide equally important and equivalent online assessment and evaluation services. Inclusion of these parallel codes would also minimize risks associated with exposure to COVID-19 and provide the best care possible during the PHE.

The Academy has identified additional opportunities for CMS to extend further flexibilities to meet its goals to protect Medicare beneficiaries and providers and continue to provide quality health care. **First, the Academy recommends CMS allow FQHCs to deliver and receive payment for group services** (such as diabetes self-management training) **via telehealth**. Existing regulations⁷ exclude group diabetes self-management training (DSMT – G0109) as a qualifying service for new or established patients. During this public health emergency, when FQHCs are dealing with potential provider shortages, any effort to introduce efficiencies in the delivery of care will reduce burden on the already strained healthcare system. Also, the ability to offer group services via telehealth may improve the mental health for seniors isolated at home.

Second, the Academy recommends CMS allow FQHCs to bill separately from their qualifying visit HCPCS codes for new and established patients for medical nutrition therapy and DSMT services provided on the same day as another billable visit. Existing regulations⁸ do not allow these qualified FQHC visits to be billed if these services are furnished on the same day as an otherwise billable visit. As care for FQHC patients shifts to the home setting and some FQHC practitioners may also be shifting their location of service to their homes, such temporary flexibility would reduce the administrative burden for FQHCs to track services being furnished on the same day for billing purposes.

5. Innovation Center Models (Section Q)

Medicare Diabetes Prevention Program (MDPP) expanded model Emergency Policy
During the novel COVID-19 pandemic, the CDC issued flexibilities to their National Diabetes
Prevention Program (NDPP) suppliers related to delivery of in person class sessions. These
flexibilities encouraged the use of alternative delivery options such as virtual make-up sessions
and offered the ability to pause offering classes if virtual make-up sessions were not an option.
The Academy agrees with CMS's response to follow the CDC's direction in allowing certain
flexibilities within the Medicare Diabetes Prevention Program (MDPP), specifically MDPP
suppliers with existing capabilities may provide services virtually, as necessary the ability to
suspend and resume at a later date in-person services, waiving limitations for virtual make-up

⁷ Specific Payment Codes for the Federally Qualified Health Center Prospective Payment System (FQHC PPS) https://www.cms.gov/medicare/medicare-fee-for-service-payment/fqhcpps/downloads/fqhc-pps-specific-payment-codes.pdf. Accessed April 30, 2020.

 $^{^8 \ \$ \ 405.2463 \ \}underline{\text{https://www.govinfo.gov/content/pkg/CFR-2014-title42-vol2/pdf/CFR-2014-title42-vol2-sec405-2463.pdf} \ Accessed \ April \ 30, \ 2020.$

sessions, and beneficiaries ability to maintain eligibility. These critical changes will help seniors improve their health and lower their risk for diabetes under the current circumstances. As noted in the April 21, 2020 letter from the Diabetes Advocacy Alliance, of which the Academy is a member, further action is needed to ensure that Medicare beneficiaries who have not already started an MDPP are able to lower their risk for diabetes in a timely manner. The Academy urges CMS to ensure that all CDC-recognized Virtual Diabetes Prevention Program providers with preliminary or full recognition be eligible for MDPP at least during this public health emergency. Additionally, CMS should allow new cohorts to begin the program without a first in-person session.

While intensive behavioral therapy (IBT) for obesity and diabetes self-management training (DSMT) benefits are not Innovation Center Models, rendering these services during the public health emergency poses similar challenges as those noted in the MDPP. Under current regulations, these services covered under Medicare Part B include clear timeframes in which beneficiaries must receive services and meet weight loss goals to remain eligible for continued services. For DSMT services, hours for the first year of service currently expire one year from the date of the first encounter. Currently, Medicare beneficiaries are unable to participate in DSMT group trainings and are losing valuable time in utilizing their full DSMT benefit within a 12-month period, especially given the uncertainty of how long this pandemic will last. For IBT for obesity services, Medicare beneficiaries are required to lose 3 kg (6.6 lbs.) during the first 6 months of treatment to be eligible to continue services for the next 6 months. For the duration of this public health emergency, the Academy urges CMS to allow "pauses" in DSMT and IBT for obesity services initiated as of March 15, 2020 and flexibilities in eligibility criteria for continuation of services consistent with the temporary changes granted for the Medicare Diabetes Prevention Program.

6. Telephone Evaluation and Management (E/M) Services (Section S)

The Academy applauds CMS's decision to no longer consider CPT codes 98966-8 (telephone assessment and management services) categorically non-covered services. Since these codes were established in 2008 by the CPT Editorial Panel and valued by the RUC, the Academy has been urging CMS to cover these services to improve timely access to care with cost effective providers and decrease unnecessary care and avoidable costs. The ability to provide a telephonic check-in offers the opportunity to determine if an MNT encounter is necessary or if adjustments to the nutrition care plan can be made over the phone, keeping the beneficiary safe at home. Other payers have already recognized the value of these services in improving patient care and managing health care costs. This decision aligns with previous decisions made by CMS to cover non-face-to-face services and recognize the importance of including family members and other caregivers in person-centered care for Medicare beneficiaries.

7. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE for the COVID-19 Pandemic (Section U)

<u>Clarify supervision requirements for certain limited incident-to billing</u>
Section U.3. includes two decisions by CMS to relax supervision requirements: (1) "to the extent NCDs and LCDs require a specific practitioner type or physician specialty to furnish a service,

procedure or any portion thereof, we are finalizing on an interim basis the chief medical officer or equivalent of the facility can authorize another physician specialty or other practitioner type to meet those requirements during the PHE for the COVID-19 pandemic and (2) "to the extent NCDs and LCDs require a physician or physician specialty to supervise other practitioners, professionals or qualified personnel, the chief medical officer of the facility can authorize that such supervision requirements do not apply during the PHE for the COVID-19 pandemic." The Academy supports these decisions as we agree they are necessary to provide continued Medicare beneficiary access to care during a time when facility and non-facility staffing decisions may impact the availability of specific practitioner types.

The NCD for intensive behavioral therapy (IBT) for obesity services is one important example of where this decision can achieve CMS's goal of continued access to high quality, cost-effective care while keeping patients and providers safe. Many RDNs provide IBT for obesity services under direct supervision of primary care providers in primary care settings. The CDC has identified several subgroups who are at higher risk for severe illness from COVID-19,9 including individuals with severe obesity. We believe this provision would remove the burdensome requirements of real-time audio/video supervision by physicians (who recognize RDNs should independently be providing these services) and ensures it will still be practicable for beneficiaries to access the full 22 sessions of the cost-effective and clinically effective IBT services they receive from RDNs that conform to the manner in which these services are provided. We ask CMS to confirm our interpretation of this provision for both the facility and non-facility (i.e. primary care provider office) settings.

8. Merit-based Incentive Payment System Updates (Section BB)

CMS has decided to apply the MIPS automatic extreme and uncontrollable circumstances policy at §414.1380(c)(2)(i)(A)(8) and (c)(2)(i)(C)(3) to MIPS eligible clinicians for the 2019 MIPS performance period/2021 MIPS payment year. The Academy appreciates the agency's recognition of the impact of COVID-19 on the ability of MIPS eligible clinicians to complete data submission as they focus on caring for patients. We also appreciate CMS's decision to extend the deadline for data submission. The current PHE and associated shifts in health care delivery present challenges in collection of some data required under measures within most performance categories. Necessary shifts in the number and roles of staff may also make it difficult to submit data for the 2020 performance period depending on the length of the PHE and recovery period. The Academy urges CMS to consider continued flexibilities for the 2020 MIPS performance period/2022 MIPS payment year. While we recognize the Quality Payment Program's budget neutrality requirement, we urge CMS to explore all possible options for payment adjustments to protect MIPS eligible clinicians from further adverse economic impacts of COVID-19.

Looking Towards the Future

Public health emergencies can occur unexpectedly or with little notice, and the chances of experiencing another pandemic is a distinct possibility. **Medicare's costs continue to rise in**

⁹CDC: Coronavirus 2019: Groups at Higher Risk for Severe Illness. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html#diabetes. Accessed April 28, 2020.

large part because our nation is paying the price for overlooking the importance of nutrition in preventing and treating costly chronic diseases. We believe that this current pandemic has exposed an opportunity to strengthen our nation's health policies and improve the nutritional status of all Americans. The world of telehealth is experiencing rapid growth and the emergence of mobile technologies designed to improve the health of individuals and enhance patient engagement should be recognized as an integral part of the long term solution to creating new opportunities for increased access to care in urban, suburban and rural areas.

COVID-19 Diagnosis among Older Americans and those with Chronic Diseases

COVID-19 has disproportionately affected some of our nations' more vulnerable citizens; those who are older and those with chronic disease (specifically individuals with diabetes, cardiovascular disease, severe obesity, chronic kidney disease, and weakened immune systems) are at higher risk for developing severe illness from COVID-19. Individuals over the age of 65 years account for over 60% of the COVID-19 related hospitalizations. Viruses such as COVID-19 can be devastating to vulnerable, nutritionally compromised populations, including those with malnutrition. According to the recent 2020 National Blueprint on malnutrition and older adults, up to 1 out of every 2 adults (65 years of age and older) are at risk for malnutrition. Older adults with chronic disease are also more likely to experience not only more severe forms of the illness but also to experience poorer outcomes (such as long term disability and frailty) which are further compounded when malnutrition is present. Research has shown the value between nutrition status and health/immunity. Whether it is another wave of COVID-19 or any other health-related public health emergency, we must be proactive and strengthen our focus on nutrition.

Nutrition Care in Chronic Disease Management

Nearly half of all Americans suffer from preventable chronic conditions, ¹³ such as obesity, diabetes, and heart disease. It is estimated that 35% of men and 40% of women in the United States have obesity ¹⁴ and that one in five Americans aged 65 years and over (one in 11 Americans overall) have been diagnosed with type 1 or type 2 diabetes. ¹⁵ Research has shown that preventive health programs are highly effective in preventing chronic diseases ¹⁶ and that a crucial component of preventative health care programs is nutrition. Data from the US Preventative Services Task Forces suggests that behavioral counseling interventions are effective in not only

¹⁰CDC: Coronavirus 2019: Groups at Higher Risk for Severe Illness. https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/groups-at-higher-risk.html#diabetes. Accessed April 28, 2020.

¹¹ CDC: Coronavirus 2019: Key Updates. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html. Accessed April 28, 2020.

 $^{^{12}}$ National Blueprint: Achieving Quality Malnutrition Care for Older. $\underline{\text{https://www.defeatmalnutrition.today/blueprint}}$ Accessed May 19, 2020.

¹³ Wullianallur R. An Empirical Study of Chronic Diseases in the United States: A Visual Analytics Approach to Public Health. Int J Environ Res Public Health. 2018 Mar; 15(3): 431.

¹⁴ US Preventative Services Task Force. Final Recommendation Statement. Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions#bootstrap-panel--4. Accessed April 28, 2020.

¹⁵ 2017 CMS Report: *Diabetes* Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over.

¹⁶National Centers for Disease Control and Prevention. www.cdc.gov/chronicdisease/programs-impact Accessed April 22, 2020.

promoting a healthful diet and physical activity (hallmarks of preventative health), but also as it relates to adults with obesity, behavioral counseling "can lead to clinically significant improvements in weight status and reduced incidence of type 2 diabetes among adults with obesity and elevated plasma glucose levels". ¹⁷ It is critical that Medicare beneficiaries have access to health care professionals (both physician and non-physician) and services that focus on disease prevention, wellness, and healthy lifestyles.

Barriers to Effective Nutrition Care Delivery via Telehealth

The current public health emergency has expanded the use of telehealth to deliver much needed medical and nutrition care services to Medicare beneficiaries. However, the current national emergency and mandates to practice social distancing have also exposed previous concerns and significant gaps in access to safe and effective nutrition care for vulnerable Medicare beneficiaries. The temporary telehealth flexibilities enacted by CMS have helped to "modernize" aspects of telehealth services under the current Medicare program.

Telehealth (and telenutrition) is firmly within RDNs' professional scope of practice; "RDNs utilize electronic information and telecommunications tools and technologies to support long-distance clinical health care which encompasses the full range of "MNT services that include disease prevention, assessment, nutrition focused physical exam, diagnosis, consultation, therapy, and/or nutrition intervention." RDNs who are equipped with technologies that allow them to assess, treat, evaluate, and monitor the nutritional status of Americans will not only strengthen prevention based programs but also will improve the ability to manage chronic conditions—chronic conditions that have placed seniors at high risk during this pandemic. The Academy urges CMS to extend current telehealth flexibilities that improve access to Medical Nutrition Therapy beyond the current pandemic to ensure that there is sufficient health care and services available by all distant site providers to meet the needs of individuals enrolled in Medicare. This is crucial to keeping Medicare beneficiaries, particularly those who are at risk or have chronic diseases, healthy.

Medical Nutrition Therapy (MNT)

Medical Nutrition Therapy (MNT) is an in-depth individualized nutrition assessment and reassessment where duration and frequency of care are determined using the Nutrition Care Process to manage and treat disease. This can include nutritional diagnostics, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian nutritionist or qualified nutrition professional.¹⁹ Registered dietitian nutritionists (RDNs) are an integral part of the health care team and routinely provide MNT focused on chronic disease prevention and treatment to Medicare beneficiaries. These interventions have been shown to either abate or to lessen the effects of chronic medical conditions. Additionally, MNT provided

¹⁷ US Preventative Services Task Force. Final Recommendation Statement: Weight Loss to Prevent Obesity-Related Morbidity and Mortality in Adults: Behavioral Interventions. https://uspreventiveservicestaskforce.org/uspstf/recommendation/obesity-in-adults-interventions. Accessed May 22, 2020.

¹⁸ Academy of Nutrition and Dietetics Quality Management Committee. Academy of Nutrition and Dietetics: Revised 2017 Scope of Practice for the Registered Dietitian Nutritionist. J Acad Nutr Diet. 2018;118(1):141-165.

¹⁹ 42 U.S.C. 1395(x)(vv)(1)

by the RDN is a widely recognized component of medical guidelines for the prevention and treatment of heart disease, diabetes, renal disease, obesity, cancers, and many other chronic diseases and conditions as well as in the reduction of risk factors for these conditions. As primary prevention, strong evidence supports optimal nutritional status as a cost-effective cornerstone in the maintenance of health, well-being, and functionality. As secondary and tertiary prevention, MNT is a cost-effective disease management strategy that reduces chronic disease risk, delays disease progression, enhances the efficacy of medical/surgical treatment, reduces medication use, and improves patient outcomes including quality of life.²⁰

The Academy urges the Secretary to exercise her authority under Section 1834 (n) (42 USC 1395(m))1 of the Social Security Act to modify the current Part B Medicare MNT benefit to include the diet-related chronic diseases Medicare beneficiaries experience as a significant step towards achieving CMS' goals of Better Care, Smarter Spending, and Healthier People. The long-term health of our nation and costs to our health care system depend on continuous, timely access to all services aimed to improve health and manage chronic diseases.

Thank you for your consideration of the Academy's comments to the Interim Final Rule: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency. Please do not hesitate to contact Jeanne Blankenship by phone at 312-899-1730 or by email at jblankenship@eatright.org or Marsha Schofield at 312-899-1762 or by email at mschofield@eatright.org with any questions or requests for additional information. The Academy looks forward to continued opportunities to work with CMS to design a health care delivery and payment system that improves the health of the nation and meets the needs of all stakeholders.

Sincerely,

Jeanne Blankenship, MS, RDN Vice President, Policy Initiatives & Advocacy

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²⁰ Grade 1 data. Academy Evidence Analysis Library, http://andevidencelibrary.com/mnt. [Grade Definitions: Strength of the Evidence for a Conclusion/Recommendation Grade I, "Good evidence is defined as: "The evidence consists of results from studies of strong design for answering the questions addressed. The results are both clinically important and consistent with minor exceptions at most. The results are free of serious doubts about generalizability, bias and flaws in research design. Studies with negative results have sufficiently large sample sizes to have adequate statistical power."