July 7, 2020

Ms. Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5531-IFC
PO Box 8016
Baltimore, MD 21244-8010

Re: CMS-5531 IFC: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

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: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program.

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

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 June 5, 2020.
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. **Scope of Practice (Section B)**
2. Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE (Section E)
3. Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (including the Patient’s Home) (Section F)
4. Durable Medical Equipment (DME) Interim Pricing in the CARES Act (Section I)
5. Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic (Section S)
6. Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency (Section CC)

### 1. Scope of Practice (Section B)

As noted in this interim final rule with comment period (IFC), CMS notes that the flexibilities around scope of practice for Non-Physician Providers (NPPs) for ordering diagnostic tests was informed by comments received in response to their request for input per Executive Order (EO) 13890 on “Protecting and Improving Medicare for Our Nation’s Seniors”. The Academy supports this action and urges CMS to issue additional flexibilities around scope of practice as noted in our January 2020 comments in response to this request that would improve Medicare beneficiary access to much needed nutrition care.

Access to RDNs and MNT is restricted for Medicare beneficiaries, particularly those who receive their primary care from NPPs. This limitation on access to nutrition care stems from both restrictive legislative and regulatory language. The Academy is currently addressing the legislative aspect via the Medical Nutrition Therapy Act of 2020 (H.R. 6971) introduced on May 22, 2020. However, a significant barrier for beneficiaries receiving essential nutrition care remains the burdensome limitation on referrals for MNT. Currently, the referral for MNT for diabetes or renal disease must come only from a physician and not from other qualified non-physician providers (clinical nurse specialists, physician assistants, nurse practitioners, and nurse midwives). This narrow ability to refer is an unfortunate limitation to access to MNT. **The Academy encourages CMS to remove this limitation that prevents NPPs from practicing at the height of their license by expanding the base of eligible referral providers for MNT utilizing any available regulatory channels.**

---

Another continued opportunity to address scope of practice limitations during the current PHE is removing the restriction on Medicare provider types eligible to provide and bill for intensive behavioral therapy (IBT) for obesity services. As noted in the Academy’s January 27, 2020 comments to CMS on the EO, the decision memorandum for IBT for obesity defines the benefit as consisting of three services falling squarely within the scope of practice of licensed or registered dietitian nutritionists or qualified nutrition professionals as part of nutrition assessments and nutrition interventions:

1. Screening for obesity in adults using measurement of BMI calculated by dividing weight in kilograms by the square of height in meters (expressed in kg/m²); and
2. Dietary (nutritional) assessment; and
3. Intensive behavioral counseling and behavioral therapy to promote sustained weight loss through high intensity interventions on diet and exercise.

The benefit has two unnecessary and overly burdensome coverage limitations that prevent RDNs and other Medicare providers from practicing at the height of their scope of practice: (1) IBT services must be provided by primary care providers and (2) IBT services must be provided in primary care settings. Notably, the United States Preventive Services Task Force specifically does not recommend IBT be limited in either manner. The Academy urges CMS to lift these arbitrary limitations to allow RDNs and others to practice at the top of their scope of practice and support Medicare beneficiary access to high quality, cost-effective care while keeping patients and providers safe.

2. Treatment of Certain Relocating Provider-Based Departments During the COVID-19 PHE (Section E)

We commend CMS on providing a mechanism that allows Medicare beneficiaries to remain in their homes and continue to receive much needed care, including MNT. We also support CMS’s decision to maintain the current payment rates which allow hospitals and health systems greater flexibilities in managing staff and resources. That being said, we ask CMS to provide clearer guidance on how to implement designating patient homes as Provider Based Departments (PBDs) during the PHE, as there is still confusion about the process for doing so as evidenced by recurring questions received weekly during CMS Office Hours and input from the Academy’s own members. Specifically, we ask CMS to outline the steps and/or documents needed to establish temporary PBD (i.e., beneficiaries’ homes) during the COVID-19 PHE.

3. Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or a Community Mental Health Center (including the Patient’s Home) (Section F)

The Academy appreciates CMS’ efforts to address delivery of hospital outpatient services during the PHE. However, the IFC incorrectly states that Medicare statute does not have a benefit category that “would allow registered dieticians [sic] the ability to directly bill Medicare for

---

their services.”

Similarly, since 2006 MNT has been on the list of Medicare approved telehealth services and RDNs have been on the list of distant site providers. We urge CMS to clarify its misstatement, which has contributed to the confusion around RDNs’ ability to provide MNT via telehealth and bill Medicare for these services.

Placing MNT as outpatient therapy services creates additional confusion. Outpatient therapy services are a distinct benefit category under Medicare Part B. Prior to the PHE these services were not on the list of Medicare approved telehealth services and physical therapists, occupational therapists and speech language pathologists were not recognized as distant site providers for telehealth services. Furthermore, the IFC and examples of services covered under this specific waiver note:

“...list of the outpatient therapy, counseling, and educational services that hospital clinical staff can furnish remotely incident to a physician’s or qualified NPP’s service [emphasis added] during the COVID-19 PHE to a beneficiary in their home or other temporary expansion location that functions as a PBD of the hospital when the beneficiary is registered as an outpatient of the hospital.”

The Medicare Part B MNT benefit specifically cannot be provided as an “incident to” service. RDNs are independent providers of MNT and guidance from CMS should accurately reflect that fact.

Diabetes self-management training (DSMT) has also been placed in the category as outpatient therapy services. The Balanced Budget Act of 1997 established Medicare coverage for DSMT services provided by a certified provider. DSMT is also an allowable service for telehealth.

Similar to MNT, DSMT is its own distinct service benefit category.

---

7 CMS-5531-IFC
9 42 CFR § 410.132
10 42 CFR, §410.134
13 CMS-5531-IFC
14 Diabetic Self-Management Training (DSMT) Accreditation Program
15 42 CFR § 410.141
16 CMS Medicare Claims Processing Manual Chapter 12 Section 190.3.6
We believe that by broadly including MNT and DSMT with outpatient therapy services during this public health emergency has contributed to confusion and in some cases, subsequent denial of valid MNT and DSMT claims for beneficiaries. The Academy urges CMS to separate these three distinct services (MNT, DSMT, and outpatient therapy services) and provide clear billing guidance for each service benefit category.

4. Durable Medical Equipment (DME) Interim Pricing in the CARES Act (Section I)

The Academy commends CMS on the actions taken to support durable medical equipment suppliers during the COVID-19 PHE. We also agree that it is in the overall interest to everyone—suppliers, health care professionals and beneficiaries alike—as suppliers will be able to maintain their inventory and be paid for items when there may be lags in care and beneficiaries may not be able to meet required visits due to the current PHE. We are concerned that Medicare beneficiaries with diabetes will face challenges in accessing their diabetes supply benefits because of unnecessarily strict documentation requirements tied to supply allocation.

Beneficiaries who do not have the capacity to participate in telehealth or attend an in-person visit with their practitioner simply cannot meet the required number of documented visits which would allow them access to much needed supplies (e.g., insulin, pump, testing strips, etc.). The unforeseen consequence of strict documentation requirements, particularly during a public health emergency, is the disruption of a beneficiary’s ability to monitor and address their blood glucose levels effectively, which ultimately places them at additional risk. We encourage CMS to work within their capacity to loosen documentation regulations surrounding diabetes supplies.

5. Application of Certain National Coverage Determination and Local Coverage Determination Requirements during the PHE for the COVID-19 Pandemic (Section S)

The American Diabetes Association estimates that 1 in every 4 healthcare dollars spent in the US is attributed to individuals who have been diagnosed with diabetes, with nearly half of that spend is directly related to diabetes care and complications. We also know that the prevalence of diabetes is continuing to grow and that individuals with diabetes are at higher risk for severe complications from a viral infection such as COVID-19 that can also have deleterious effects on glycemic control. The Academy commends CMS’s decision to waive enforcement of the clinical indications for therapeutic continuous glucose monitors (CGM) in local coverage determinations, thus allowing all beneficiaries with diabetes access to continuous glucose monitoring (CGM). Not only does this provision allow for higher quality serum glucose data but it also empowers the beneficiary to better monitor blood glucose levels and adjust medication doses from home, and it makes interactions with providers more meaningful and effective, especially during this time of social distancing and limited in-person visits. We are concerned, however about what will happen to beneficiaries who are currently allowed to utilize CGM during the PHE and are then made to return to the original restrictive requirements. Some patients will lose the ability to use the CGM once the COVID-19 flexibilities have passed and thus lose their ability to manage their diabetes with one of the most effective tools currently available. CMS has recognized “that the use of therapeutic continuous glucose monitors may allow patients to proactively treat

---

their diabetes,” which ultimately supports patients reaching and maintaining serum glycemic targets, an important component in diabetes standard of care. The Academy supports the use of CGM when clinically appropriate and believes that allowing a wider range of beneficiaries with diabetes access monitoring tools such as CGM will lead to better care. **The Academy urges CMS to extend this waiver beyond the end of the PHE as the benefits of doing so are not limited to the constraints imposed by the current pandemic and so will continue to apply.**

6. Payment for Remote Physiologic Monitoring (RPM) Services Furnished During the COVID-19 Public Health Emergency (Section CC)

The Academy supports CMS’ decision to allow—on an interim basis—RPM services to be reported for periods of time that are fewer than 16 days of 30 days, but no less than 2 days for the reasons cited in the IFC. Specific to CPT codes 99453, 99454, and 99457, RDNs routinely monitor physiologic parameters such as weight as part of MNT services to evaluate the nutrition care plan and revise as needed. These actions are squarely within the RDN’s scope of practice and conform with the Academy’s evidence-based nutrition practice guidelines for persons with diabetes and chronic kidney disease. As such, **the Academy asks CMS to allow RDNs to bill for these services during the current PHE.** In addition, when CMS first established coverage for these CPT codes in the CY 2019 PFS final rule, they noted they would be issuing further guidance to help practitioners and stakeholders determine the scope of service and better interpret the code descriptors, including the types of technology that can be used to provide these services. To our knowledge such guidance has never been issued and we urge CMS to do so to support the practitioner community.

The Academy would also like to take the opportunity to reiterate our comments made on June 1, 2020 to CMS in response to CMS-1744-IFC: Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, included below. We are looking forward to continued partnership with CMS in delivering safe and effective nutrition care to Medicare beneficiaries now and after the public health emergency.

**Looking Towards the Future**

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

---

to rise in 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 nation’s 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 to reduce associated risks of mortality and morbidity.

Nutrition Care in Chronic Disease Management

Nearly half of all Americans suffer from preventable chronic conditions, such as obesity, diabetes, chronic kidney disease (CKD), and heart disease. It is estimated that 35% of men and 40% of women in the United States have obesity 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. Financially, there is a huge cost associated with caring for older Americans with chronic disease. It is estimated that individuals with CKD and/or end-stage renal disease account for 33.8% of total Medicare fee-for-service (FFS) spending and 61% of health care costs associated with diabetes.

---


29 2017 CMS Report: Diabetes Occurrence, Costs, and Access to Care among Medicare Beneficiaries Aged 65 Years and Over.

are generated from individuals who are > 65 years of age\textsuperscript{17}. Research has shown that preventive health programs are highly effective in preventing chronic diseases\textsuperscript{31} 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 generally promoting a healthful diet and physical activity (hallmarks of preventative health), but also as treatment for 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”.\textsuperscript{32} It is critical that Medicare beneficiaries have access to the type of effective health care professionals (both physician and non-physician) and services that are demonstrated to help beneficiaries achieve 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.”\textsuperscript{33} 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 sufficient health care and services are 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 diagnostic, therapy, and counseling services for the purpose of disease management that are furnished by a registered dietitian nutritionist or other qualified nutrition professional.\textsuperscript{34} 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 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.\textsuperscript{35} The Academy urges the Secretary to exercise his authority under Section 1834 (n) (42 USC 1395(m))\textsuperscript{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 effective 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; Additional 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    Marsha Schofield, MS, RD, LD, FAND
Vice President, Policy Initiatives & Advocacy  Senior Director, Governance
Academy of Nutrition and Dietetics    Academy of Nutrition and Dietetics

\textsuperscript{34} 42 U.S.C. 1395(x)(vv)(1)
\textsuperscript{35} 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.”]