

June 16, 2025

Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-0042-NC P.O. Box 8013 Baltimore, MD 21244-8013

RE: CMS-0042-NC Delivered Electronically via Regulations.gov

Dear Administrator Oz:

WW International, Inc ("WWI") and WW Clinic, PLLC ("WW Clinic"), a medical group affiliated with and managed by WWI (together, "WeightWatchers"), appreciate the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) in response to "Request for Information; Health Technology Ecosystem" [CMS-0042-NC] ("RFI"). WeightWatchers deploys digital delivery of evidence-based services to prevent, manage and treat the chronic conditions of overweight and obesity. More than 3 million individuals use the traditional WeightWatchers behavior change program through a variety of media - via digital app, over the Internet, and through in-person coaching sessions. And over the last two years, the WW Clinic offering has been providing medical weight loss services through a telehealth platform to tens of thousands of individuals. All of our programs are grounded in evidence-based research, which can be found at our online science center.

WeightWatchers is committed to supporting individuals in achieving and maintaining optimal health through evidence-based services. Our services help people manage their weight and reduce the severity of weight-related chronic illness. WeightWatchers is the global leader in widely accessible and affordable clinical weight management, as well as healthy lifestyle and multi-component behavioral counseling to achieve weight management. With more than 60 years of experience and over 175 studies published, we have operated a continuous innovation model of service delivery based on scientific evidence. We use research-based methods that evolve as new science emerges, to achieve long-term changes in eating, activity, and body weight. Our mission is to apply the best science to an affordable and scalable delivery system that is accessible by all.

We offer the following responses to several of the questions (those focused on use of digital apps and tools) posed by the RFI.

B. Patients and Caregivers

PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs as well as the actions you should take?

PC-3. Are you aware of health management, care navigation, or personal record apps that would be useful to Medicare beneficiaries and their caregivers? PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

C. Providers

1. Digital Health Apps

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved digital health products for their patients?

As a lifelong partner for those living with obesity, we are focused on helping to improve our patients' health and quality of life. Studies have shown that quality of life significantly improves when people experience a statistically significant reduction in weight. This is not surprising, as more than forty percent (40%) of adults in the U.S. have obesity and are poised to develop a wide range of weight-related chronic diseases that significantly impact our population and fuel our nation's health costs. Those with obesity have health costs that are 42% higher than those with healthy weight.

Our own research and experience confirm the strong and long-standing clinical finding that treating obesity leads to a beneficial cascade of health and quality of life improvements. Based on a 6-month randomized controlled trial (n=376) that compared participants following our WeightWatchers Points[®] Program, to those given standard nutritional guidelines alone, the WeightWatchers group showed significantly better improvements in overall weight-related quality of life and in the domains of self-esteem, sexual life, and physical functioning.⁵

¹ Jensen MD et al. 2013 AHA/ACC/TOS guidelines for the management of overweight and obesity in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. Circulation 2013.

² Centers for Disease Control and Prevention. FastStats: Adult Obesity Facts. Obesity. May 14, 2024. Accessed at: index.html Accessed June 12, 2025.

³ Centers for Disease Control and Prevention. Adult Obesity Causes & Consequences. https://www.cdc.gov/obesity/adult/causes.html August 29, 2017. Accessed June 12, 2025.

⁴ Centers for Disease Control and Prevention. Adult Obesity Facts. May 14, 2024. Access at: <u>index.html</u>. Accessed on June 12, 2025.

⁵ Based on a 6-month randomized controlled trial (n=376) that compared participants following WW to those given standard nutritional guidelines alone, and the WW group showed significantly better improvements in the self-esteem, sexual life, and physical functioning subscales and overall score of weight-related quality of life. Palacios et al. 2025. Manuscript under review. Funded by WW International, Inc.

Our consumer research, which we conduct regularly, consistently finds that people want access to weight health tools and services, including digital health tools and products, but many of these tools and services do not fall within the traditional categories of services that are covered by insurance. Coverage of the full range of evidence-based obesity and weight health treatments, including digital treatments, is desperately needed. Providers cannot leverage, recommend, refer to, or use digital health products, and consumers cannot access these tools, because coverage policies are outdated and exclude weight health services. Specifically, Medicare coverage policy does not cover, support or promote evidence-proven treatment for obesity or overweight, particularly when it is delivered through digital delivery systems. Both the virtual delivery of intensive behavioral therapy and effective medications to manage obesity, as well as treatment related to such medications, which is often provided through virtual, telehealth specialty providers such as WW Clinic, are excluded from Medicare coverage. Specifically,

- ✓ The Medicare National Coverage Decision (NCD) on intensive behavioral therapy (IBT) for healthy lifestyle to treat obesity is not aligned with evidence that clearly indicates the efficacy of digital delivery, especially in the weight management space. In CMS's recent review of the Medicare Diabetes Prevention Program, it was shown that, among those who attended their sessions primarily in person, the average weight loss was 4.6%, compared with an average weight loss of 5.3% among those who attended sessions virtually. The current coverage requirements for IBT, which do not permit coverage for virtual care, clearly do not take into consideration the clear advantages of digital health products. This disconnect is not surprising, as the coverage policies have not been updated in over twelve years.
- ✓ The Medicare NCD requires intensive behavioral therapy for obesity to be delivered in person by primary care providers. These providers are:
 - Not trained to provide this service.
 - Do not have the office set up to deliver this service.
 - Are often not accessible to patients living in rural areas.
- ✓ Further, Medicare Part D, permits the exclusion of anti-obesity medications because they are inappropriately deemed "weight loss agents" rather than treatment for obesity, which has been deemed a chronic disease since June 2013 when AMA's House of Delegates issued its formal policy based on science.

⁶ Final Evaluation Report, Evaluation of Medicare Diabetes Prevention Program, at 29 (Mar. 2025).

✓ And, the Medicare's Diabetes Prevention Program (MDPP), which is a form of IBT for those with pre-diabetes and therefore could help a subset of those with obesity or overweight, contains serious limits to the accessibility and usability.

We urge CMS to:

✓ Provide coverage for telehealth-based comprehensive, whole person, obesity treatment, including all forms of treatment and programs that address this chronic condition, such as IBT and MDPP. As a nationwide telehealth provider, WW Clinic, alongside WeightWatchers, offers a comprehensive weight health management program that is available in all 50 states and the District of Columbia, providing access to crucial healthcare services for the more than 200 million adults in the US who could benefit from care for their obesity or overweight with a comorbidity. Our own numbers show that people have been engaging with our virtual health services.

The WeightWatchers workshop is a foundational piece of the behavioral portion of our offering. At our Workshops, expert coaches traditionally have met with groups of members at one of our thousands of studio locations across the country. There, individuals learn weekly techniques for weight loss in a welcoming, judgment-free zone, providing a community for support of their weight health journey. While we have been offering in-person Workshops for over 60 years, we also launched virtual workshops in 2021. Since then, we've seen virtual attendance grow to over 70,000 attendances weekly, on average, with some individual events drawing up to 8,000 attendees. This growth shows how virtual services in the weight health space are much desired and growing at a fast pace.

Demand for virtual services exists in all areas of the country - both urban and rural. By supporting telehealth services through more flexible coverage that allows for technical innovation, such as broader coverage for asynchronous chat services, much needed access to services will be increased. Our WW Clinic offering exemplifies the demand and the need for services in rural, and other non-urban areas. Of the more than 100,000 WW Clinic patients (as of March 2025) served through our telehealth platform, approximately 85% live outside of urban areas, including 20% who live in rural areas, where we bring to the doorstep specialty obesity services that would not otherwise be accessible. Academic centers, where this type of specialty service often resides, are not always easy to reach and typically have months-long waits for appointments. Improving coverage for telehealth services that address chronic diseases like obesity is an essential step toward holistically addressing a condition that plays a significant role in the morbidity and mortality rates in the US.

- ✓ Revise the Medicare NCD on intensive behavioral therapy for healthy lifestyle to allow and activate coverage for digital and virtual delivery of the service. The effectiveness and benefits of virtual delivery of the service is fully supported by extensive evidence reviews conducted by the US Preventive Health Services Task Force recommendations.⁷ Additionally, this type of permanent coverage would be consistent with the current regulatory regime, which allows IBT services to be provided by primary care providers through live-synchronous telehealth until September 2025, pursuant to the current telehealth waivers.⁸
- ✓ Revise Medicare policies generally to address obesity as a chronic disease, the treatment of which also can address other comorbidities, such as diabetes.

CMS should revise the Part D coverage policy to properly classify obesity as a chronic disease, and require coverage of at least one drug in each class of drugs that treat obesity. Such policies are consistent with longstanding AMA and evidence-based guidelines supporting treatment of obesity as a disease. ^{9,10,11}

Additionally, CMS should adopt modifications to the MDPP expanded pilot to allow for better accessibility and useability of this important benefit for those with obesity or overweight who also have elevated blood sugar, placing them at risk for diabetes. As one of the most prevalent chronic and costly conditions amongst our nation's seniors, preventing diabetes is proven, through the Medicare pilot, to both improve quality of life and significantly reduce health care costs.¹²

<u>Concluding Thoughts: Consumer-Facing Design is Essential to Success and Must be</u> Built in from the Outset

It is essential that CMS include, from the outset and early in design of policies and programs, consideration of entities that directly serve consumers. These entities bring

⁷ United States Preventive Services Task Force, US Department of Health and Human Services.

⁸ The Continuing Appropriations and Extensions Act, 2025 (H.R. 1968), signed into law 3/15/2025.

⁹ Kyle TK, Dhurandhar EJ, Allison DB. Regarding Obesity as a Disease: Evolving Policies and Their Implications. Endocrinol Metab Clin North Am. 2016 Sep;45(3):511-20. doi: 10.1016/j.ecl.2016.04.004. PMID: 27519127; PMCID: PMC4988332.

¹⁰ Consensus Statement on Obesity as a Disease, accessed on 1/7/25 at: https://stop.publichealth.gwu.edu/obesity-statement.

¹¹ Recognition of Obesity as a Disease H-440.842, accessed on 1//7/25 at: https://policysearch.ama-assn.org/policyfinder/detail/obesity?uri=%2FAMADoc%2FHOD.xml-0-3858.xml

¹² Office of the Actuary, Centers for Medicare and Medicaid Services, "Certification of Medicare Diabetes Prevention Program", March 14, 2026. accessed ib 6/16/25 at: <u>Diabetes-Prevention-Certification-2016-03-14.pdf</u>

consumer-based design using the best available science and evidence. By tapping into the experience and knowledge of direct-to-consumer businesses that are tackling the complex issues related to digital health, vital learnings can be examined to create the best possible policies and programs.

Creating services, delivered digitally, online, or in person that effectively engage patients, support behavior change, and drive health outcomes is what WeightWatchers does. We have teams of designers, engineers, and behavioral scientists who are focused on delivering human-centered, science-based strategies to effect behavior change and deliver best-in-class obesity treatment. Our company's purpose is to inspire weight health for real life. We do that best at the intersection of consumer insights and behavioral science.

Private sector adoption of continuous innovation service models that are developed and updated based on behavioral science are essential. We believe that if comprehensive coverage for evidence-based treatment for obesity and overweight existed, payers would require an evidence base, pilots, and continuous evaluations of outcomes which drive science-based innovation.

We appreciate the opportunity to provide input on improving the Medicare program so that it effectively addresses obesity, which is one of the major health crises of our day, by offering insurance-covered access to digital health products that effectively treat, manage, and prevent obesity.

Please feel free to contact Jacquie Cooke at <u>Jacquie.Cooke@WW.com</u> or more information or to answer any questions regarding the response to this RFI.

Sincerely,

/S/ Jacquie Cooke Chief Legal and Administrative Officer

/S/ Kim Boyd, MD Chief Medical Officer