Herrin Nutrition Services

Counseling/Education

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May 2, 2022

TO: State of Vermont, Green Mountain Care Board (hereinafter called "State"), and Herrin Nutrition Services, LLC

Re: Examination of the relevant Literature 4/22/22-5/1/22

From: Marcia Herrin of Herrin Nutrition services, LLC

Dr. Herrin has agreed to provide a Written Opinion under oath no later than May 1, 2022: Contractor shall review the Kahm Clinic's CON application and responses to questions in Docket No. GMCB-009-21con. These materials are available on the State's website at https://gmcboard.vermont.gov/CON/GMCB-009-21con.

Contractor shall prepare and deliver to the State a written opinion that includes the following:

1. Personal details: name, current post, summary of previous experience, dietetic registration number, current licenses to practice.
2. All publications authored by Dr. Herrin within the past 10 years.
3. A list of all cases in which Dr. Herrin has testified as an expert at trial or by deposition in the previous four years.
4. An introduction and a description of Dr. Herrin's qualifications to provide a professional opinion regarding the use of the metabolic testing device and the body composition analysis device (the devices) within PHPs and IOPs for the treatment of eating disorders.
5. Professional opinion regarding the use of the metabolic testing device and the body composition analysis device (the devices) within PHPs and IOPs for the treatment of eating disorders.
6. An explanation of the focus of eating disorder treatment within PHPs and IOPs.
7. A review of the literature that describes the information generated by the devices and how this information can be applied in the treatment of individuals with eating disorders in PHPs and IOPs.
8. An opinion as to whether the use of the devices is inconsistent with or contrary to evidence-based practice in the treatment of eating disorders within a PHP or IOP.
9. The pros and cons, including the potential harm, if any, of using these devices in these programs.

1. Personal details: name, current post, summary of previous experience, dietetic registration number, current licenses to practice.
    a. Marcia Herrin, EdD, MPH, RDN, LD, FAED
    b. Registered dietitian nutritionist
    c. Doctorate in Nutrition Education, Columbia University
    d. Masters of Public Health Nutrition, University of California, Berkeley
    e. Fellow of the Academy of Eating Disorders
    f. Proprietor and clinician, Herrin Nutrition Services, LLC
    g. 40 years experience in the field of dietetics (see previously submitted CV)
    h. 35 years of clinical experience in treating eating disorders
    i. Clinical Assistant Professor of Pediatrics, Geisel School of Medicine at Dartmouth
    j. Co-author of two seminal books in the field of nutrition counseling in the treatment of eating disorders:
        i. Nutrition Counseling in the Treatment of Eating Disorders, 2 editions, 3rd edition in press
        ii. Parent's Guide to Eating Disorders, 2 editions
    k. Academy of Nutrition and Dietetics Dietitian Nutritionist Registration Number 585307
    l. Licensed to practice dietetics in New Hampshire, Vermont, Massachusetts
2. All publications authored by Dr. Herrin within the past 10 years.
    a. *Guidebook for Nutrition Treatment of Eating Disorders, Academy of Eating Disorders, 2020*
    b. *Nutrition Counseling in the Treatment of Eating Disorders*, 2nd edition 2013
    c. *Nutrition Counseling in the Treatment of Eating Disorders, 3rd edition, in press*
3. A list of all cases in which Dr. Herrin has testified as an expert at trial or by deposition in the previous four years.
    a. None
4. An introduction and a description of Dr. Herrin's qualifications to provide a professional opinion regarding the use of the metabolic testing device and the body composition analysis device (the devices) within PHPs and IOPs for the treatment of eating disorders.
    a. Dietitian Dr. Marcia Herrin, who has a doctorate in nutrition education and master's in public health nutrition, is the founder of Dartmouth College's nationally renowned eating disorder treatment program for college students. She is a Clinical Professor at Dartmouth's Medical School with an appointment in the Adolescent Medicine Faculty and provides training to Pediatric Residents at Children's Hospital at Dartmouth. Besides lecturing worldwide on nutrition counseling in the treatment of eating disorders, Dr. Herrin provides programmatic and clinical supervision for eating disorder providers in the US, United Arab Emirates, Britain, Mexico, Russia, Ukraine, and Venezuela.
    b. Dr. Herrin is a Fellow of the Academy of Eating Disorders. As a Fellow she collaborates with the most respected worldwide researchers and clinicians in the field of eating disorders, including clinician administrates who manage PHPs and IOPs.

5. Professional opinion regarding the use of the metabolic testing device and the body composition analysis device (the devices) within PHPs and IOPs for the treatment of eating disorders.
    a. These medical machines are not necessary to curing malnutrition in the treatment of eating disorders at any level of care including PHPs and IOPs.They are not recommended by the Academy of Eating Disorders or the American Dietetic Association (now the Academy of Nutrition and Dietetics) or by Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs.
    b. Practice guidelines and other standards in the treatment of eating disorders do not include Metabolic testing and BIA as recommended treatment modalities.
    c. More research is needed to validate Metabolic Test (indirect calorimetry) instruments to assess validity and reliability both in technical equipment and for measuring human participants.
    d. The accuracy and clinical value of metabolic testing and body composition analysis devices is not established.
6. An explanation of the focus of eating disorder treatment within PHPs and IOPs.
    a. Traditionally, these programs provide access to a structured, safe treatment environment for those suffering from eating disorders who need more support than standard outpatient therapy offers, but are not in need of a full residential experience. Most of the treatment is in a group setting and may include supervised meal preparation, meal supervision and support, supervised exercise, shopping experiences, and other therapies such as art. Some programs offer multi-family group therapy.
    b. New skills developed can be immediately applied to real-life situations. Patients can stay connected to and build support in family, peers and often school settings.
    c. These programs provide a “step-down” from residential care and a “step-up” from individual outpatient treatment and are less costly than higher levels of care.
    d. PHPs and IOPs have demonstrated efficacy in the treatment of eating disorders though only a few programs have examined long-term outcomes across diagnoses. Several studies demonstrated significant improvements in weight, ED psychopathology, and comorbid symptoms.
    e. PHPs and IOPs have increased utility currently with the long wait lists for admittance to residential programs.
        i. Friedman K, Ramirez AL, Murray SB, Anderson LK, Cusack A, Boutelle KN, Kaye WH. A Narrative Review of Outcome Studies for Residential and Partial Hospital-based Treatment of Eating Disorders. Eur Eat Disord Rev. 2016 Jul;24(4):263-76. doi: 10.1002/erv.2449. Epub 2016 Apr
        ii. Baudinet, J., & Simic, M. (2021). Adolescent eating disorder day Programme treatment models and outcomes: a systematic scoping review. Frontiers in psychiatry, 539.

iii. Brown, T. A., Cusack, A., Anderson, L. K., Trim, J., Nakamura, T., Trunko, M. E., & Kaye, W. H. (2018). Efficacy of a partial hospital programme for adults with eating disorders. European Eating Disorders Review, 26(3), 241-252.

7. A review of the literature that describes the information generated by the devices and how this information can be applied in the treatment of individuals with eating disorders in PHPs and IOPs.
    a. Most commercially Metabolic Testing devices do not give accurate or reliable results (Delsoglio et al., 2020). Kaviani et al. (2018) tested 8 indirect calorimetry instruments including Cosmed instruments and concluded the same: "Several indirect calorimetry (IC) instruments are commercially available, but comparative validity and reliability data are lacking. Existing data are limited by inconsistencies in protocols, subject characteristics, or single-instrument validation comparisons. New generations indirect calorimeters may prove more accurate (Delsoglio et al., 2020). The usefulness of Metabolic Testing in treatment of eating disorders has not been confirmed. In a literature review, only one study (Kochavi et al., 2020) was found that tested the relevance of metabolic testing using an indirect calorimetry machine (Deltatrac metabolic monitor) in the treatment of 60 hospitalized patients with anorexia nervosa and bulimia. The researchers concluded that "measured REE cannot be used to assess the required caloric intake of patients with AN during renourishing, hence it is likely not clinically useful in the planning of nutritional rehabilitation in these patients." The well documented changes in fluid balances that occur in renourishing eating disordered patients likely contributes to the impracticality metabolic testing for these patients. The authors conclude, "Thus, clinical judgment seems still to be the best approach in the planning of nutritional rehabilitation of patients with AN (anorexia nervosa)."
        i. Kaviani, S., Schoeller, D. A., Ravussin, E., Melanson, E. L., Henes, S. T., Dugas, L. R., ... & Cooper, J. A. (2018). Determining the accuracy and reliability of indirect calorimeters utilizing the methanol combustion technique. Nutrition in clinical practice, 33(2), 206-216.
        ii. Delsoglio, M., Dupertuis, Y. M., Oshima, T., van der Plas, M., & Pichard, C. (2020). Evaluation of the accuracy and precision of a new generation indirect calorimeter in canopy dilution mode. Clinical nutrition, 39(6), 1927-1934.
        iii. Kochavi, B., Mendelowitsch, S., Enoch-Levy, A., Yaroslavsky, A., Toledano, A., Modan-Moses, D., & Stein, D. (2020). Resting energy expenditure in acutely ill and stabilized patients with anorexia nervosa and bulimia nervosa. International Journal of Eating Disorders, 53(9), 1460-1468.

b. The accuracy and clinical value of body composition analysis machines is not established. The major problem in their use in the assessment and treatment and in eating disorders is that results from BIA machines rely on assumptions based on populations mean values and cannot be applicable to all patients (Ward, 2019). A recent study by Popiołek et al. (2019), is the first study to compare anthropometrical and BIA parameters in 46 patients diagnosed with anorexia nervosa. This group found that BIA correlated well with BMI. The researchers did not investigate the same parameters for healthy controls. The authors concluded that selected BIA and anthropometrical parameters could be used for AN patients' assessment and then during in the recovery process but studies have not yet been conducted to assess the efficacy of BIA. Using BMI and BMI percentages for age for child and adolescent patients is part of standard treatment for eating disorders at all levels of care. An excellent paper by Cindy Bulik (Abbaspour et al., 2021) of University of North Carolina and her international research team compared DEXA scans to BIA in adult patients with anorexia nervosa (AN). They concluded that at this point the DEXA should remain the universal standard, as the BIA equations need future validation and may not be suitable for low weight and possibly dehydrated eating disordered patients. These authors concluded that "despite ease and cost in both access and operation, the suitability of BIA in low bodyweight populations remains questionable and that further research is needed to confirm not only the possibility of using BIA in patients with AN."
    i. Ward, L. C. (2019). Bioelectrical impedance analysis for body composition assessment: reflections on accuracy, clinical utility, and standardisation. European journal of clinical nutrition, 73(2), 194-199.
    ii. Popiołek, J., Teter, M., Kozak, G., Powrózek, T., Mlak, R., Karakuła-Juchnowicz, H., & Małecka-Massalska, T. (2019). Anthropometrical and Bioelectrical Impedance Analysis Parameters in Anorexia Nervosa Patients' Nutritional Status Assessment. Medicina, 55(10), 671.
    iii. Abbaspour, A., Reed, K. K., Hübel, C., Bulik-Sullivan, E. C., Tang, Q., Bulik, C. M., & Carroll, I. M. (2021). Comparison of Dual-Energy X-ray Absorptiometry and Bioelectrical Impedance Analysis in the Assessment of Body Composition in Women with Anorexia Nervosa upon Admission and Discharge from an Inpatient Specialist Unit. International journal of environmental research and public health, 18(21), 11388.
c. My review of the literature provided in this application and of the literature on this topic does not identify empirical studies that supports the use of these devices in any level of care. I have contacted a number of the most respected eating disorder programs (ERC, the Emily Program, Alsana, and Veritas Collaborative) in the country to find out if these programs use these devices in their PHP and IOP programs. They are not being used. One comment: "this practice does not align with evidence or best-practices at this time. These device do not add any new information or clarity to a well-trained RD's assessment ability." Another comment: "There are no IOP, PHP, Res, or IP - that I am aware

of that utilized these tests regularly in treatment. It is not included in any way in the REDC centers of excellence white paper" (Residential Eating Disorder Centers of excellence white paper, 2021)."

8. An opinion as to whether the use of the devices is inconsistent with or contrary to evidence-based practice in the treatment of eating disorders within a PHP or IOP.
    a. These medical machines are not necessary to curing malnutrition in the treatment of eating disorders. They are not recommended by the Academy of Eating Disorders or the American Dietetic Association (now the Academy of Nutrition and Dietetics) or by Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs. References below:
9. The pros and cons, including the potential harm, if any, of using these devices in these programs.
    a. Eating disordered patients are already, by definition, anxious about gaining weight. As there are no studies on the effect of having metabolic and body composition being regularly measured in this population, it is reasonable to assume that the test itself will increase anxiety and worry about how metabolism and percentage of fat and muscle are changing due to treatment. Will the patient develop a dependence on having regular metabolic and body composition tests?
    b. If metabolic testing and body composition devices were validated and evidence-based, their use would be most appropriate for inpatient treatment when meals are prepared by staff overseen by a dietitian with precise amounts of various nutrients and calories rather than in an PHP and IOP where one to two meals a day are prepared and consumed off-site. The clinical examples provided in the Kahm application seem to imply that nutrition and calorie needs are very precise. Patients participating in an IOP and PHP will be living at home and neither they nor their families will be or should be counting or measuring macronutrients or calories in such an exact way to meet the goals dictated by devices.
    c. Standard evidenced-based treatment does not rely on Metabolic Testing or Body Composition Analysis. These measures are not necessary and may not be accurate. A well trained dietitian can adjust a patient's food plan based on weight changes on a simple scale to achieve the same results. Patients in IOP and PHP programs usually discharge to home treatment teams: a primary care provider, therapist, and dietitian. No providers outside of the Kahm Clinic use these devices. Therefore, the use of these devices is likely to make the transition to a home treatment team more difficult for patients who have become accustomed to being tested by these devices. The patients will have observed their treatment and food plan are adjusted based on the results of the testing.
    d. Although I was not asked to comment on the Kahm application response to Q5 and Q6 (20220216_ResptoQ002.pdf (vermont.gov)) which clearly states that the PHP and IOP programming for adolescents will include FBT, I did. (See my full comments and references on page 14-15 of my review of the Kham Clinic's CON application.) The reliance of medical devices by a dietitian for determining

calorie levels and components of meals runs counter to the basic premises of Family-Based Treatment for anorexia and bulimia (FBT). FBT's unique approach is that it empowers parents and other caregivers to take charge of their child's food intake. Another key tenet of FBT is that the clinician takes a nonauthoritarian therapeutic stance but active role in guiding the family through the recovery process, but does not tell the family exactly how to feed their child. Rather, the clinician collaborates with the family by helping them figure out for themselves the best way to refeed their child.

e. In conclusion, I believe these machines are unnecessary to curing malnutrition in eating disorder patients and may cause dependence on machines that are not available in any other treatment milieu. Further use of these machines in PHPs and IOPs that employ FBT techniques is at odds with the basic tenets of FBT.

Review of the Kahm Clinic's CON application & responses to questions in Docket No. GMCB-009-21con

Application: All articles cited in the Application can be found at: Kahm Clinic Supporting Documents.pdf (vermont.gov)

Reviewed, summarized, and comments by Marcia Herrin (in italics) 4/22/22-5/1/22

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20211118_Application.pdf (vermont.gov)

Footnotes 15-21 on pages 17-19 (Use of devices) (Footnotes 19 and 20 are from, "Measuring Health from the Inside," written by Annika Kahm and Carolyn Chaffee. Applicant forgot to note the full cite or Ibid for Footnote 20. It appears that Footnote 21 is also from the same source.)

- Devices: Application at page 2 and CON Standard 3.22 at pages 16-18.
- Footnotes 1-14 on pages 1-15.

Summary of Footnotes

Page 1, footnote 1

[1] McBain, Ryan K., Nicole K. Eberhart, Joshua Breslau, Lori Frank, M. Audrey Burnam, Vishnupriya Kareddy, and Molly M. Simmons, Transforming Mental Health Care in the United States. Santa Monica, CA: RAND Corporation, 2021. https://www.rand.org/pubs/research_briefs/RBA889-1.html. (Articles cited in footnotes are collectively attached as Exhibit 1)

Summary of footnote 1:
Embeddable Summary: How to Transform Mental health Care in the United States

Promote pathways to care
Improve access to care
Establish evidence-based continuum of care

Page 3, footnotes 2-5

[2] Klump KL, Bulik CK, Kaye W, Treasure J, Tyson E. Academy for Eating Disorders Position Paper: Eating Disorders are Serious Mental Illnesses. Int J Eat Disord. 2009 Mar;42(2):97-103. doi: 10.1002/eat.20589. (This is an excellent and brief article overviewing the medical complications and social costs of eating disorders)

[3] Galmiche, M., Dechelotte, P., Lambert, G., & Tavolacci, M. P. (2019). Prevalence of eating disorders over the 2000-2018 period: a systematic literature review. *American Journal of Clinical Nutrition*, 109(5), 1402-1413; Hoek, H. W. (2016). Review of the worldwide epidemiology of eating disorders. *Current Opinion in Psychiatry,* 29(6), 336–339.

[4] Arcelus, J., Mitchell, A. J., Wales, J., & Nielsen, S. (2011). Mortality rates in patients with anorexia nervosa and other eating disorders: a meta-analysis of 36 studies. *Archives of General Psychiatry*, *68*(7), 724-731; Chesney, E., Goodwin, G. M., & Fazel, S. (2014). Risks of all-cause and suicide mortality in mental disorders: a meta-review. *World Psychiatry*, 13(2), 153-160; Udo, T., Bitley, S., & Grilo, C. M. (2019). Suicide attempts in US adults with lifetime DSM-5 eating disorders. *BMC Medicine*, 17, 120.

[5]https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1267/2021/01/State-Report_Vermont.pdf

Summary of footnotes 2-5:
Overview of the medical complications, mortality rates, and social costs of eating disorders.

Page 4, footnote 6

[6]https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1267/2020/07/Social-Economic-Cost-of-Eating-Disorders-in-US.pdf "The value of reduced wellbeing for people with EDs was also estimated. While the loss of wellbeing is not a financial cost, reduced quality of life due to impaired functioning and premature death that result from EDs was measured in monetary terms by multiplying a value of a statistical life year (VSLY) by the years of healthy life lost using the burden of disease methodology.3 Inputs for this modelling study were largely drawn from previous academic literature where greater emphasis was placed on nationally representative studies (e.g. rather than studies in insured populations alone)."

Summary of footnote 6:
Reviews research on reduced wellbeing for people with eating disorders.

Page 10, cited literature, footnote 7

- The American Psychological Association has identified five levels of care that include intensive outpatient and partial hospitalization programs as steps up to bridge the distance from outpatient care to residential or full hospitalization. *See*, Yager, Joel & Devlin, Michael & Halmi, Katherine & Herzog, D.B. & III, J.E. & Powers, P. & Zerbe, K.J. (2006). Practice guideline for the treatment of patients with eating disorders third edition. *American Journal of Psychiatry*. 163. 1-128.

- Clinical trials have demonstrated that day treatment programs are more effective than traditional outpatient treatment with outcomes similar to residential treatment. *See*, Hepburn, Z., Wilson, K. (2014). Effectiveness of adult day treatment for eating disorders. *Mental Health Review Journal*, 19(2), 131-144. 10.1108/MHRJ-01-2013-0003.

- Partial hospitalization programs are a cost-effective alternative to residential programs for patients with an acuity too high for traditional outpatient care. *See*, Hayes, N. A., Welty, L. J., Slesinger, N., & Washburn, J. J. (2019). Moderators of treatment outcomes in a partial hospitalization and intensive outpatient program for eating disorders. *Eating disorders*, *27*(3), 305–320. 10.1080/10640266.2018.1512302.

- Day programs enable patients to encounter everyday life situations that can impact eating choices, enabling patients to practice and develop better long-term coping behaviors. *See*, Zipfel, S., Reas, D.L., Thornton, C., Olmsted, M.P., Williamson, D.A., Gerlinghoff, M., Herzog, W. and Beumont, P.J. (2002), Day hospitalization programs for eating disorders: A systematic review of the literature. *International Journal of Eating Disorders*, 31: 105-117. https://doi.org/10.1002/eat.10009.

[7] Hepburn, Z., Wilson, K. (2014). Effectiveness of adult day treatment for eating disorders. *Mental Health Review Journal*, 19(2), 131-144. 10.1108/MHRJ-01-2013-0003.

Summary of cited literature, footnote 7:
Reviews effectiveness of day treatment programs, PHPs, and IOPs.

Page 11, footnotes 8-11

[8] Hayes, N. A., Welty, L. J., Slesinger, N., & Washburn, J. J. (2019). Moderators of treatment outcomes in a partial hospitalization and intensive outpatient program for eating disorders. *Eating disorders*, *27*(3), 305–320. 10.1080/10640266.2018.1512302

[9] Austin, A., Flynn, M., Richards, K., Hodsoll, J., Duarte, T. A., Robinson, P., Kelly, J., & Schmidt, U. (2021). Duration of untreated eating disorder and relationship to outcomes: A systematic review of the literature. *European eating disorders review: the journal of the Eating Disorders Association*, *29*(3), 329–345. https://doi.org/10.1002/erv.2745

[10] Zipfel, S., Reas, D.L., Thornton, C., Olmsted, M.P., Williamson, D.A., Gerlinghoff, M., Herzog, W. and Beumont, P.J. (2002), Day hospitalization programs for eating disorders: A systematic review of the literature. *International Journal of Eating Disorders*, 31: 105-117. https://doi.org/10.1002/eat.10009

[11] Hepburn and Wilson, 2014.

Summary of footnotes 8-11:
Reviews effectiveness of day treatment programs, PHPs, and IOPs.
Note: unable to evaluate footnote 11 as reference is incomplete.

Page 12, footnotes 12, 13

[12] Ibid.

[13] Berg, K. C., Peterson, C. B., Frazier, P., & Crow, S. J. (2012). Psychometric evaluation of the eating disorder examination and eating disorder examination-questionnaire: A systematic review of the literature. International Journal of Eating Disorders, 45(3), 428–438. doi:10.1002/eat.20931; Luce, K. H., & Crowther, J. H. (1999). The reliability of the eating disorder examination- self report questionnaire version (EDE-Q). International Journal of Eating Disorders, 25, 349–351. doi:10.1002/(SICI)1098-108X(199904)25:33.3.CO;2-D; Machado, P. P., Martins, C.,Vaz,A. R., Conceicao, E., Bastos, A. P., & Goncalves, S. (2014). Eating disorder examination questionnaire: Psychometric properties and norms for the Portuguese population. European Eating Disorders Review, 22(6), 448–453. doi:10.1002/erv.2318.

Summary of footnote 12:
Unable to evaluate footnote 12 as reference is incomplete.

Summary of footnote 13:
Evaluation of the eating disorder examination questionnaire.

Page 15, footnote 14

[14] American Dietetic Association. Position of the American Dietetic Association: Nutrition intervention in the treatment of anorexia nervosa, bulimia nervosa, and other eating disorders. J Am Diet Assoc. 2006 Dec;106(12):2073-82. doi: 10.1016/j.jada.2006.09.007. PMID: 17186637.

Summary of footnote 14:
Describes standard nutrition interventions in the treatment of eating disorders. Metabolic testing and BIA are not mentioned.

Page 17, footnotes 15-17

[15] Herman Pontzer, *Burn: New Research Blows the Lid Off How We Really Burn Calories, Lose Weight, and Stay Healthy.* New York: Random House, 2021, p. 67-8.

[16] On the validity of this device see the Quark RMR Validation Papers cited by CosMed at Validation_papers_QuarkRMR_print.pdf (cosmed.com).

[17] Saladino CF. The efficacy of Bioelectrical Impedance Analysis (BIA) in monitoring body composition changes during treatment of restrictive eating disorder patients. J Eat Disord. 2014 Dec 4;2(1):34. doi: 10.1186/s40337-014-0034-y. PMID: 25485109; PMCID: PMC4258054.

Summary of footnote 15:
Short history of indirect calorimetry: since 1800 measuring oxygen consumption and CO_2 production were used to measure calories burned.

Summary of footnote 16:
Six Validation papers (dates of publication 2011-2016) provided by CosMed for obese, healthy, and mechanically ventilated patients.

Comment: Most commercially available indirect calorimeters do not give accurate or reliable results (Delsoglio et al., 2020). Kaviani et al. (2018) tested 8 indirect calorimetry instruments including Cosmed instruments and concluded the same: "Several indirect calorimetry (IC) instruments are commercially available, but comparative validity and reliability data are lacking. Existing data are limited by inconsistencies in protocols, subject characteristics, or single-instrument validation comparisons. The aim of this study was to compare accuracy and reliability of metabolic carts using methanol combustion as the cross-laboratory criterion. future research will be needed using a similar or preferably larger scale approach of validating IC (indirect calorimetry) instruments, to further assess validity and reliability both in technical equipment and for measuring human participants." New generations indirect calorimeters may prove more accurate (Delsoglio et al., 2020).

Kaviani, S., Schoeller, D. A., Ravussin, E., Melanson, E. L., Henes, S. T., Dugas, L. R., ... & Cooper, J. A. (2018). Determining the accuracy and reliability of indirect calorimeters utilizing the methanol combustion technique. Nutrition in clinical practice, 33(2), 206-216.
Delsoglio, M., Dupertuis, Y. M., Oshima, T., van der Plas, M., & Pichard, C. (2020). Evaluation of the accuracy and precision of a new generation indirect calorimeter in canopy dilution mode. Clinical nutrition, 39(6), 1927-1934.

Summary of footnote 17:
This paper is not a review of the efficiacy of using BIA in the treatment of eating disorder patients. Saladino, the author, did a literature review and found 10 papers where body composition in eating disordered patients was assessed by BIA. None of these papers reported on studies using BIA in a treatment program or BIA efficacy in improving treatment. Rather Saladino concluded, "Therefore, in the hands of a qualified clinician who understands the instrumentation as well as human metabolism, it appears that BIA could be a very useful modality in the treatment of patients afflicted with restrictive eating disorders." Saladino's paper was published 8 years ago and still no randomized controlled trial (RCT) have been published using BIA in the treatment of eating disorders.

Page 18, footnotes 18-20

[18] Marwan El Ghoch, Marta Alberti, Carlo Capelli, Simona Calugi, Riccardo Dalle Grave, "Resting Energy Expenditure in Anorexia Nervosa: Measured versus Estimated", Journal of Nutrition and Metabolism, vol. 2012, Article ID 652932, 6 pages, 2012. https://doi.org/10.1155/2012/652932. For more literature on eating disorders and metabolic testing see Compés, Cristina & Ruiz, A & Velasco, Cristina & Breton, Irene & Camblor, Miguel & García-Peris, "How accurate are predictive formulas calculating energy expenditure in adolescent patients with anorexia nervosa?", Clinical Nutrition, vol. 26, 6 pages, 2006. DOI: 10.1016/j.clnu.2006.09.001; Van Wymelbeke V, Brondel L, Marcel Brun J, Rigaud D. Factors associated with the increase in resting energy expenditure during refeeding in malnourished anorexia nervosa patients. Am J Clin Nutr. 2004 Dec;80(6):1469-77. doi: 10.1093/ajcn/80.6.1469. PMID: 15585757; Winter TA, O'Keefe SJ, Callanan M, Marks T. The effect of severe undernutrition and subsequent refeeding on whole-body metabolism and protein synthesis in human subjects. JPEN J Parenter Enteral Nutr. 2005 Jul-Aug;29(4):221-8. doi: 10.1177/0148607105029004221. PMID: 15961676.

[19] *Measuring Health from the Inside*, Annika Kahm, MS and Carolyn Hodges Chaffee, MS, RD (Friesen Books, 2015).

[20]

Summary of footnote 18:
This paper was published in 2012. Resting Energy Expenditure was estimated using a Cosmed device, called FitMate. The authors studied 15 patients with anorexia nervosa but no controls and conclude their date needs to be confirmed by other studies.

Summary of footnote 19:
Kahm and Chaffee's book does not include any published results from their 50 years of using these devices to treat eating disordered patients.

Summary of footnote 20:
Unable to evaluate footnote 20 as reference is incomplete.

Page 19, footnote 21
Summary of footnote 21:
Unable to evaluate footnote 21 as reference is incomplete.

20220118_ResptoQ001.pdf (vermont.gov)

1. Devices: Response to Q 12.

12. Page 13: Explain in detail the large searchable dataset that will help the Kahm Clinic to continually improve their treatment methodology. Provide specific examples.

Comment: The current dataset which is not described should be evaluated for its utility in assessing effectiveness of the treatment.

2. Footnotes 1-5.

Page 9, footnotes 1-2

[1] Zipfel, S., Reas, D.L., Thornton, C., Olmsted, M.P., Williamson, D.A., Gerlinghoff, M., Herzog, W. and Beumont, P.J. (2002), Day hospitalization programs for eating disorders: A systematic review of the literature. *International Journal of Eating Disorders*, 31: 105-117. https://doi.org/10.1002/eat.10009

[2] Hepburn and Wilson, 2014.

Summary of footnote 1:
A 20-year-old paper describing the clinical benefits of day hospitals.

Summary of footnote 2:
Unable to evaluate due to incomplete reference.

Page 12, footnote 3

[3] Klump KL, Bulik CK, Kaye W, Treasure J, Tyson E. Academy for Eating Disorders Position Paper: Eating Disorders are Serious Mental Illnesses. Int J Eat Disord. 2009 Mar;42(2):97-103. doi: 10.1002/eat.20589. (This is an excellent and brief article overviewing the medical complications and social costs of eating disorders) This was included in the original application.

Summary of footnote 2:
Agreed this is an excellent overview of medical and social costs of eating disorders.

Page 13, footnotes 4-5:

[4]https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1267/2021/01/State-Report_Vermont.pdf
[5]https://cdn1.sph.harvard.edu/wp-content/uploads/sites/1267/2020/07/Social-Economic-Cost-of-Eating-Disorders-in-US.pdf "The value of reduced wellbeing for people with EDs was also estimated. While the loss of wellbeing is not a financial cost, reduced quality of life due to impaired functioning and premature death that result from EDs was measured in monetary terms by multiplying a value of a statistical life year (VSLY) by the years of healthy life lost using the burden of disease methodology.3 Inputs for this modelling study were largely drawn from previous academic literature where greater emphasis was placed on nationally representative studies (e.g. rather than studies in insured populations alone)."

Summary of footnote 4:
Social and economic costs of eating disorders in Vermont calculated by STRIPED (Strategic Training Initiative for Prevention of Eating Disorders) based on US Census Bureau statistics (2018).

Summary of footnote 5:
Social and economic costs of eating disorders in the United States of America. Report for the Strategic Training Initiative for Prevention of Eating Disorders and the Academy for Eating Disorders, 2020.

20220216_ResptoQ002.pdf (vermont.gov)

1. Devices: Response to Q 1 a-g.

1. **Page 17-18: It is stated that Metabolic Testing Devices and Body Composition Devices are both useful in the treatment of eating disorders, noting that neither is widely used oravailable in the majority of hospitals.**

a. **Explain in more detail the specific information generated from each device.**

Metabolic Testing Devices

Comment re: Metabolic Testing Devices
More research is needed to validate Metabolic Test (indirect calorimetry) instruments to assess validity and reliability both in technical equipment and for measuring human participants (Kaviani et al., 2018).

Kaviani, S., Schoeller, D. A., Ravussin, E., Melanson, E. L., Henes, S. T., Dugas, L. R., ... & Cooper, J. A. (2018). Determining the accuracy and reliability of indirect calorimeters utilizing the methanol combustion technique. Nutrition in clinical practice, 33(2), 206-216.

Body Composition Analysis machines

Comment re: Body Composition Analysis (BIA) machines:
The accuracy and clinical value of body composition analysis machines is not established. The major problem in their use in the assessment and treatment and in eating disorders is that results from BIA machines rely on assumptions based on populations mean values and cannot be applicable to all patients (Ward, 2019).

Ward, L. C. (2019). Bioelectrical impedance analysis for body composition assessment: reflections on accuracy, clinical utility, and standardisation. European journal of clinical nutrition, 73(2), 194-199.

b. Identify each traditional treatment modality and how information from each devise is used and/or integrated into each treatment modality for eating disorders.

Below is the answer to the question of how these devices are integrated into nutrition treatment of eating disorders from the Kahm application:

Our dieticians use these medical machines as tools to help to cure malnutrition. Curing malnutrition makes therapy more effective: a starved brain cannot do the grueling therapeutic work required to get to the psychological root of the eating disorder. The machines are not used differently in each modality, but they make each modality more effective. It is physiological groundwork that enables the psychological work to be effective.

Comment: These medical machines are not necessary to curing malnutrition in the treatment of eating disorders. They are not recommended by the Academy of Eating Disorders or the American Dietetic Association (now the Academy of Nutrition and Dietetics) or by Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs. References below:

Academy of Eating Disorders in its Medical Care Standards Committee in its Eating Disorders: A Guide to Medical Care. (2021) and Guidebook for Nutrition Treatment of Eating Disorders (2020) available at https://www.aedweb.org/publications.
Ozier, A. D., & Henry, B. W. (2011). Position of the American Dietetic Association: nutrition intervention in the treatment of eating disorders. Journal of the American Dietetic Association, 111(8), 1236-1241.
American Dietetic Association. (2006). Position of the American Dietetic Association: Nutrition intervention in the treatment of anorexia nervosa, bulimia nervosa, and other eating disorders. Journal of the American Dietetic Association, 106(12), 2073-2082.
Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs, Comprehensive Accreditation Manual for Behavioral Health Care, 2016, The Joint Commission, Joint Commission Perspectives®, January 2016, Volume 36, Issue 1..

Metabolic Testing Devices

Comment:

The usefulness of Metabolic Testing in treatment of eating disorders has not been confirmed. In a literature review, only one study (Kochavi et al., 2020) was found that tested the relevance of metabolic testing using an indirect calorimetry machine (Deltatrac metabolic monitor) in the treatment of 60 hospitalized patients with anorexia nervosa and bulimia. The researchers concluded that "measured REE cannot be used to assess the required caloric intake of patients with AN during renourishing, hence it is likely not clinically useful in the planning of nutritional rehabilitation in these patients." The well documented changes in fluid balances that occur in renourishing eating disordered patients likely contributes to the impracticality metabolic testing for these patients. The authors conclude, "Thus, clinical judgment seems still to be the best approach in the planning of nutritional rehabilitation of patients with AN (anorexia nervosa)."

Kochavi, B., Mendelowitsch, S., Enoch-Levy, A., Yaroslavsky, A., Toledano, A., Modan-Moses, D., & Stein, D. (2020). Resting energy expenditure in acutely ill and stabilized patients with anorexia nervosa and bulimia nervosa. International Journal of Eating Disorders, 53(9), 1460-1468.

Body Composition Analysis machines

Comment:

A recent study by Popiołek et al. (2019), is the first study to compare anthropometrical and BIA parameters in 46 patients diagnosed with anorexia nervosa. This group found that BIA correlated well with BMI. The researchers did not investigate the same parameters for healthy controls. The authors concluded that selected BIA and anthropometrical parameters could be used for AN patients' assessment and then during in the recovery process but studies have not yet been conducted to assess the efficacy of BIA. Using BMI and BMI percentages for age for child and adolescent patients is part of standard treatment for eating disorders at all levels of care.

An excellent paper by Cindy Bulik (Abbaspour et al., 2021) of University of North Carolina and her international research team compared DEXA scans to BIA in adult patients with anorexia nervosa (AN). They concluded that at this point the DEXA should remain the universal standard, as the BIA equations need future validation and may not be suitable for low weight and possibly dehydrated eating disordered patients. These authors concluded that "despite ease and cost in both access and operation, the suitability of BIA in low bodyweight populations remains questionable and that further research is needed to confirm not only the possibility of using BIA in patients with AN."

Popiołek, J., Teter, M., Kozak, G., Powrózek, T., Mlak, R., Karakuła-Juchnowicz, H., & Małecka-Massalska, T. (2019). Anthropometrical and Bioelectrical Impedance Analysis Parameters in Anorexia Nervosa Patients' Nutritional Status Assessment. Medicina, 55(10), 671.

Abbaspour, A., Reed, K. K., Hübel, C., Bulik-Sullivan, E. C., Tang, Q., Bulik, C. M., & Carroll, I. M. (2021). Comparison of Dual-Energy X-ray Absorptiometry and Bioelectrical Impedance Analysis in the Assessment of Body Composition in Women with Anorexia

Nervosa upon Admission and Discharge from an Inpatient Specialist Unit. International journal of environmental research and public health, 18(21), 11388.

c. **Explain in detail if and how the same kinds of information generated by each device can be obtained through other means such as through lab work, including comprehensive metabolic panels etc. for use in eating disorder treatment for adults and adolescents. Address the costs and the pros and consof using these two devices to generate information relative to the cost of conducting lab work on a regular basis, including comprehensive metabolic panels, etc.**

Comment: The relevant clinical data in the treatment of an eating disorder that is recommended by the Academy of Eating Disorders in its Medical Care Standards Committee in its Eating Disorders: A Guide to Medical Care. (2021) and the Guidebook for Nutrition Treatment of Eating Disorders (2020) available at https://www.aedweb.org/publications is:

- *Comprehensive metabolic panel for all patients*
- *Vital sign (lying and standing heart rate and blood pressure, body weight, body temperature)*
- *Electrocardiograms (if indicated by vitals)*
- *Calculation of weight suppression*
- *Growth history in child and adolescent patients.*

The frequency of labs and other medical tests depends on the severity of the eating disorder.

Note: Regular weight checks provide the same clinical information as metabolic and body composition analysis tests. The Academy of Eating Disorders does not recommend or mention metabolic and body composition analysis tests in either of its two guidebooks on the treatment of eating disorders: The Guide to Medical Care, Fourth edition (2021) and Guidebook for Nutrition Treatment of Eating Disorders (2020).

*The Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs (2016), Elements of Performance for CTS.02.03.11, C 1. D recommends for organizations that provide non-*24-hour eating *disorders care, treatment, or services:*
After admitting an individual to its program, the organization performs or makes a documented referral for the following tests, screenings, and procedures based on the needs of the individual served and in a time frame that meets the needs of the individual and is consistent with organization policy:

- *Complete blood count*
- *Comprehensive serum metabolic profile, including phosphorus and magnesium*
- *Thyroid function test*
- *Electrocardiogram (ECG), if clinically indicated*
- *Body Mass Index (BMI)*
- *Heart rate*

  Note: For non–24-hour settings, the program may accept test results from other providers completed within two weeks prior to admission.

The Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs, Comprehensive Accreditation Manual for Behavioral Health Care, 2016, The Joint Commission, Joint Commission Perspectives®, January 2016, Volume 36, Issue 1,2016.

d. **Explain in detail whether the IOP and PHP programs for adults and adolescents will also utilize regular lab work to include comprehensive metabolic panels. Explain how the results from lab work will be used the same or differently for treatment of adults and adolescents in the IOP and PHPprograms.**

*Comment: The Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs (2016) Elements of Performance for CTS.02.03.11, C 1. D clearly recommends that for organizations that provide non-*24-hour eating *disorders care, treatment, or services: After admitting an individual to its program, the organization performs or makes a documented referral for the following tests, screenings, and procedures based on the needs of the individual served and in a time frame that meets the needs of the individual and is consistent with organization policy:*

- *Complete blood count*
- *Comprehensive serum metabolic profile, including phosphorus and magnesium*
- *Thyroid function test*
- *Electrocardiogram (ECG), if clinically indicated*
- *Body Mass Index (BMI)*
- *Heart rate*

  Note: For non–24-hour settings, the program may accept test results from other providers completed within two weeks prior to admission.

  The Joint Commission Requirements for Residential and Outpatient Eating Disorders Programs, Comprehensive Accreditation Manual for Behavioral Health Care, 2016, The Joint Commission, Joint Commission Perspectives®, January 2016, Volume 36, Issue 1,2016.

e. **Confirm whether the existing Kahm Clinic currently leases the MetabolicTesting and the Body Composition devices.**

The machines are not leased but owned outright.

No comment.

d. **Explain in detail whether the IOP and PHP programs for adults and adolescents will also utilize regular lab work to include comprehensive metabolic panels. Explain how the results from lab work will be used the same or differently for treatment of adults and adolescents in the IOP and PHPprograms.**

e. **Confirm whether the existing Kahm Clinic currently leases the MetabolicTesting and the Body Composition devices.**

The machines are not leased but owned outright.

f. **Please include peer reviewed support for any assertion in the table below that a device is considered evidence-based practice.**

g. **Please complete the table below.**

	Metabolic Testing Device	Body Composition Device
Is the device considered an evidence-based practice? Yes or No.	As cited in the application, "Unfortunately, this technology is not available in the majority of the hospitals, because it requires skilled technicians and sophisticated methodologies that are costly and difficult to apply in standard clinical settings."[1] The authors say it is "unfortunate," because the evidence points to that this technology should be used more than it is in hospital settings, i.e., eating disorder treatment would be better if people were willing to invest in the machinery and their staff to be able to use it properly.	As noted in the original application, in terms of research, one article summarizing the literature on Body Composition Analysis (the technical name is Bioelectrical Impedance Analysis, BIA) concludes that "the literature indicates that the use of Bioelectrical Impedance Analysis (BIA) in eating disorder patients to be efficacious in determining body composition during the treatment period, and that only assessing weight changes does not necessarily reflect specific changes in various body compartments. Also, utilizing BIA has the advantage of using each patient as his/her "control", potentially allowing for a more individualized nutrition regimen according to the body composition changes observed during treatment."[2]

Comment: Footnote 1 first cites the 10-year old Italian study by Drs El Ghoch and Dalle Grave of 15 subjects with anorexia nervosa exploring whether the Cosmed Fitmate method was comparable to the Douglas bag method and the Mueller et al. equation in measuring resting energy expenditure (REE). It is the Douglas bag method and the Mueller equation, which requires a dexascan, that require skilled technicians and sophisticated methodologies. These authors do not say that evidence points to using Metabolic Test devices in the treatment of eating disorders. They state the well known fact that one often used REE prediction equation, the Harris-Benedict equation, is not accurate in eating disorder patients: "Unfortunately, data available on AN patients indicate that Harris-Benedict equation overestimates REE. More recent papers (Kaviani, 2018) conclude that the indirect calorimetry (IC) instruments that are commercially available lack comparative validity and reliability data. Furthermore, these instruments have not be validated for use in eating disorder patients. The El Ghoch study does not answer the question of whether it is essential in the treatment of eating disorders to measure REE. Furthermore, the standards of care cited throughout this expert opinion and my clinical experience conclude that measuring REE is not essential to the best treatment. To say it simply, if the

underweight patient is losing weight on a calorie controlled diet, then increase the calorie level of the diet.

Kaviani, S., Schoeller, D. A., Ravussin, E., Melanson, E. L., Henes, S. T., Dugas, L. R., ... & Cooper, J. A. (2018). Determining the accuracy and reliability of indirect calorimeters utilizing the methanol combustion technique. Nutrition in clinical practice, 33(2), 206-216.

Footnote 1:

[1] Marwan El Ghoch, Marta Alberti, Carlo Capelli, Simona Calugi, Riccardo Dalle Grave, "Resting Energy Expenditure in Anorexia Nervosa: Measured versus Estimated", Journal of Nutrition and Metabolism, vol. 2012, Article ID 652932, 6 pages, 2012. https://doi.org/10.1155/2012/652932.

Summary: This paper was published in 2012. Resting Energy Expenditure was estimated using a Cosmed device, called FitMate. The authors studied 15 patients with anorexia nervosa, but did not have controls and conclude their date needs to be confirmed by other studies.

Footnote 1, other citations:

Compés, Cristina & Ruiz, A & Velasco, Cristina & Breton, Irene & Camblor, Miguel & García-Peris, "How accurate are predictive formulas calculating energy expenditure in adolescent patients with anorexia nervosa?", Clinical Nutrition, vol. 26, 6 pages, 2006. DOI: 10.1016/j.clnu.2006.09.001;

Summary: As others have found that the predictive formulas overestimate resting energy expenditure in anorexia nervosa patients compared to indirect calorimetry. These researchers conclude "indirect calorimetry may be a useful tool for calculating caloric requirements in these patients."

Van Wymelbeke V, Brondel L, Marcel Brun J, Rigaud D. Factors associated with the increase in resting energy expenditure during refeeding in malnourished anorexia nervosa patients. Am J Clin Nutr. 2004 Dec;80(6):1469-77. doi: 10.1093/ajcn/80.6.1469. PMID: 15585757;

These authors document the well known increase in resting energy expenditure during refeeding of anorexia nervosa patients. In this study energy expenditure was measured using indirect calorimetry technique.

Winter TA, O'Keefe SJ, Callanan M, Marks T. The effect of severe undernutrition and subsequent refeeding on whole-body metabolism and protein synthesis in human subjects. JPEN J Parenter Enteral Nutr. 2005, Jul-Aug;29(4):221-8. doi: 10.1177/0148607105029004221. PMID: 15961676.

This study used total carbon dioxide production and oxygen consumption were measured in the rested, fasted state by means of indirect calorimetry, using a metabolic monitor (MedGraphics CPX/D, St Paul, MN).

Footnote 2:

Saladino CF. The efficacy of Bioelectrical Impedance Analysis (BIA) in monitoring body composition changes during treatment of restrictive eating disorder patients. J Eat Disord. 2014 Dec 4;2(1):34. doi: 10.1186/s40337-014-0034-y. PMID: 25485109; PMCID: PMC4258054.

Summary:
Saladino, the author, in a literature review found 10 papers where body composition in eating disordered patients was assessed by BIA. None of these papers reported on studies using BIA in a treatment program or BIA efficacy in improving treatment. Rather Saladino concluded, "Therefore, in the hands of a qualified clinician who understands the instrumentation as well as human metabolism, it appears that BIA could be a very useful modality in the treatment of patients afflicted with restrictive eating disorders." Saladino's paper was published 8 years ago. Since its publication no randomized controlled trials (RCT) have been published using BIA in the treatment of eating disorders.

Q5& Q6

5. **In a table format, provide a detailed IOP and PHP Treatment Schedule by hour for: a) adults and b) adolescents. (NOTE: Treatment Schedules were provided in the applicationfor IOP and PHP programs but it was not clear whether the schedules were only for the adult programs. Also, the IOP treatment schedule did not show treatment activities from 6:00 p.m. to 7:00 p.m.)**

The programming is not different so there is no need for a different schedule. Different topics within the program will arise, of course, and the programing will be presented differently for adolescents as is appropriate for their age, but the structure is the same. The only difference on the IOP schedule that we included with the original application is that the CBT group would be a FBT group. (As Donna Jerry and I discussed on the phone previously, the 7-8pm time is a typo; it should read 6-7pm – my apologies).

6. **Family therapy is not reflected in the application for adult or adolescents. Please explain.**

This is a mistake and oversight on our part. FBT will certainly be part of our adolescent treatment. There is considerable scholarly debate on its value for treating adults and because of this the emphasis of those programs will be CBT and DBT.

Comment: The Kahm application response to Q5 and Q6 as stated above (20220216_ResptoQ002.pdf (vermont.gov)) clearly states that the PHP and IOP programming for adolescents will include FBT. The reliance of medical devices by a dietitian for determining calorie levels and components of meals runs counter to the basic premises of Family-Based Treatment for anorexia and bulimia (FBT). FBT is well known for being the most effective evidence-based treatment approach for adolescent eating disorders (Lock & Le Grange, 2019). FBT's unique approach is that it empowers parents and other caregivers to take charge of their child's food intake. Body weight is measured at each visit and the results provided to parents and child. Parents are given the responsibility for deciding what their child eats, how much is eaten, when it is eaten. Parents are to monitor all food intake and physical

activity, much like a treatment team would do on an inpatient unit. Parents are encouraged by clinicians to act on the premise: "You know how to feed and take care of your child." Another key tenet of FBT is that the clinician takes a nonauthoritarian therapeutic stance but active role in guiding the family through the recovery process, but does not tell the family exactly how to feed their child. Rather, the clinician collaborates with the family by helping them figure out for themselves the best way to refeed their child.

Lock, J., & Le Grange, D. (2019). Family-based treatment: Where are we and where should we be going to improve recovery in child and adolescent eating disorders. International Journal of Eating Disorders, 52(4), 481-487.
Lock, J. (2018). Family therapy for eating disorders in youth: current confusions, advances, and new directions. Current opinion in psychiatry, 31(6), 431-435.
Rienecke, R. D. (2017). Family-based treatment of eating disorders in adolescents: current insights. *Adolescent health, medicine and therapeutics*, *8*, 69.
Lock, J., & Le Grange, D. (2013). Treatment manual for anorexia nervosa: A family-based approach (2nd ed.). New York: Guilford Press.
Le Grange, D., & Lock, J. (2007). Treating bulimia in adolescents: A family- based approach. New York: Guilford Press.

APA levels of ED treatment (vermont.gov) (Response to Q003)

- Devices: Response to Q 2, 3b, 5, 6a, 9a.
- No footnotes.

Q2

2. **In a table format, for calendar year 2020 and 2021, note the number of individuals serve number of tests completed using the Metabolic Testing device, the number of tests completed using the Body Composition Device, and the number of tests performed on ea device that were reimbursed by insurance companies.**

Comment:
As metabolic testing and body composition devices are only used in 4 clinics in the US (according to Kalm website), it is understandable that these tests may not be reimbursed by insurance.

Q3b

b. during the period of treatment, specify the proposed frequency of testing using: 1)Metabolic Testing Device and 2) the Body Composition Device for i) the adult PHP; ii) adult IOP; iii) adolescent PHP; and iv) adolescent IOP programs.

	Adult PHP	Adult IOP	Adolescent IOP
Body Composition Analysis	1 or 2 times/week	1 or 2 times/week	1 or 2 times/week
Metabolic Testing	One every 4-6 weeks	Once every 4-6 weeks	Once every 4-6 weeks

Comment:
Eating disordered patients are already, by definition, anxious about gaining weight. As there are no studies on the effect of having body composition being regularly measured in this population, it is reasonable to assume that the test itself will increase anxiety and worry about how the percentage of fat and muscle are changing due to treatment and, likely, dependence on having body composition regularly measured. If metabolic testing and body composition devices were validated and evidence-based, their use would be most appropriate for inpatient treatment when meals are prepared by staff overseen by a dietitian with precise amounts of various nutrients and calories.

Q5

5. **Explain in detail the extent of use the of lab work and metabolic panels in the adult PHP and IOP programs and the adolescent PHP and IOP programs. Please explain how the information provided by the metabolic testing body composition devices affects the clinic's use of lab work and metabolic panels. We need a better understanding of how theprogram will utilize labs and the two devices in treating eating disorders and whether onewill be relied on more frequently than the other to inform the course of patient treatment.**

A comprehensive metabolic panel (CMP) is not required for eating disorder treatment. It is a blood test that typically measures a variety of different markers such as blood sugar, electrolytes, kidney function and liver function. This is important for the treatment of eating disorders at higher levels of care to monitor any symptoms of refeeding syndrome or other medical complications while increasing food intake; however, a CMP is completely different from a Metabolic Test as done at The Kahm Clinic.

Comment:
The Academy for Eating Disorders Medical Care Standards Committee in its Eating Disorders: A Guide to Medical Care. (2021) recommends a comprehensive metabolic panel for all patients with a suspected eating disorder. The Academy of Eating Disorders does not recommend or mention The Academy of Eating Disorders does not recommend or mention BIA or Metabolic Testing in either of its two guidebooks on the treatment of eating disorders: The Guide to Medical Care and Guidebook for Nutrition Treatment of Eating Disorders (2020).

Q6a

6. **Explain in detail for each device how and whether the Metabolic Testing Device and the Body Composition Device are considered to be evidence-based practice in the treatmentof eating disorders.**

We have already provided literature of empirical studies from well-respected peer reviewed scholarly journals for both devices. The fact that they are not widely used does not mean that they are not evidence based.

   a. **In addition, please respond to the concern that a therapeutic practice that focuses on monitoring weight and evaluating body composition may not be an evidence-based approach to treating eating disorders, as they are a mental health issue.**

Comment:
My review of the literature provided in this application and of the literature on this topic does not identify empirical studies that supports the use of these devices. I have contacted a number of the most respected eating disorder programs (ERC, the Emily Program, Alsana, and Veritas Collaborative) in the country to find out if these programs use these devices in their PHP and IOP programs. They are not being used. One comment :"this practice does not align with evidence or best-practices at this time. These device do not add any new information or clarity to a well-trained RD's assessment ability." Another comment: "There are no IOP, PHP, Res, or IP -

that I am aware of that utilized these tests regularly in treatment. It is not included in any way in the REDC centers of excellence white paper" (Residential Eating Disorder Centers of excellence white paper, 2021)."

Note: Residential Eating Disorder Centers (REDC) was formed in December, 2011 to serve as a professional association of eating disorder treatment providers, focused on standards, policy, research, ethics, and best practices. Originally, REDC stood for as the Residential Eating Disorders Consortium, as all REDC members were eating disorder treatment programs offering 24/7 care. In 2020, REDC expanded the name and membership to include all higher levels of care, and is now the consortium representing eating disorders care across all higher levels of care. Membership in REDC is open to eating disorder programs offering a higher level of care treatment including Inpatient, Residential, PHP (Partial Hospital Program or Day Treatment), and/or IOP (Intensive Outpatient Program) levels of care and meeting REDC established standards. REDC represents about 80% of the higher level of care for eating disorders delivered in the US underscoring REDC's position as a key voice representing the entire spectrum of eating disorders care.
https://redcconsortium.org
https://redcconsortium.org/wp-content/uploads/2021/11/ED-Center-of-Excellence-White-Paper-Updated-2021.pdf

Q9a (includes Kahm application response)

9. **Please explain whether and how Kahm Clinic's treatment of eating disorder patients, both currently and as proposed in the PHP and IOP programs, differs from its work in general nutrition, sports nutrition, management, and prediabetes.**
    a. **Are there differences in the focus and philosophy of treatment, and the languageused with patients?**

The focus, regardless of who is being seen, is always healthy behaviors and helping individuals fuel their body best given their unique life circumstances. However, eating disorder patients offer particular challenges. Because the disease is psychosomatic, there is a larger mental health aspect of treatment. We are always working closely with multidisciplinary treatment teams with our eating disorder patients. And we see eating disorder patient much more frequently than our other patients since they need to be seen more often. One notable difference between eating disorder patients and non-eating disordered patients is also the use of blind weights as well as the numbers from the body composition analysis. With an eating disorder patient, they never know the actual numbers, but we only speak to them of the trends so that they know if they are progressing or regressing. With an athlete, for instance, we will happily let them know that they have gained 10lbs and that 9 of those, for instance, were muscle.

The focus and philosophy will be different than our current practice. Currently we only specialize in dietetics as such our goal is to do that as well as we can. However, that will only be one part of our goal in the new program, which, of course, involves much more than simply dietetics.

Comment:
The basic approach of the Kahm Clinic's treatment with a focus on multidisciplinary treatment teams appears to be evidenced-based.

20220324_ResptoQ004.pdf (vermont.gov)

- Devices: Response to Q 2, 4.

- No footnotes. Submission does include The Joint Commission, Eating Disorders Standards for Behavioral Health Care. Page 26-42.

Q2

2. **Response to Questions submitted on February 16, 2022, Question 1: In your response, you identify what the Metabolic Test Device and the Body Composition Analysis Device measure. Using specific examples, explain how the information measured by each deviceis then used in the treatment of patients in the proposed IOP and PHP programs.**

Comment:
Standard evidenced-based treatment does not rely on Metabolic Testing or Body Composition Analysis. These measures are not necessary and may not be accurate. A well trained dietitian can adjust a patient's food plan based on weight changes on a simple scale to achieve the same results. The examples given here imply that nutrition, calorie needs area very precise. Patients participating in an IOP and PHP will be living at home and neither they nor their families will be or should be counting or measuring macronutrients or calories in such an exact way to meet the goals dictated by devices. Patients in IOP and PHP programs usually discharge to home treatment teams: a primary care provider, therapist, and dietitian. The fact that providers will not be using the Kalm clinic devices is likely to make the transition to a home treatment team difficult for patients who become accustomed to these being tested by these devices and the knowledge that their treatment and food plan are adjusted based on the results of the testing.

Q4

4. **In response to question 2 in your March 7, 2022 submission, it is stated that, "In Vermont, but not in other states, the testing is generally not covered by insurance. Identify other states in New England where commercial and/or Medicaid do providereimbursement for the Metabolic Testing device and the Body Composition device.**

Comment:
I am not able to comment on whether insurance covers this kind of testing in any state.

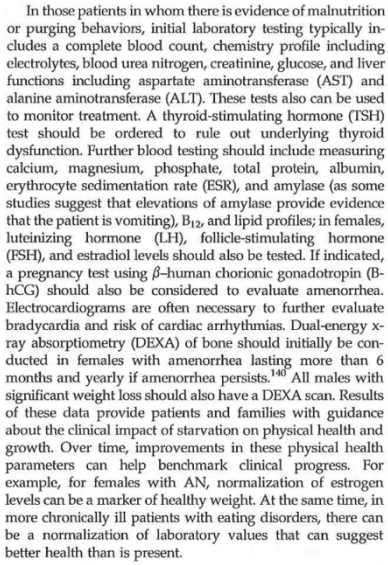
- No footnotes. Submission does include The Joint Commission, Eating Disorders Standards for Behavioral Health Care, 2016. Page 26-42.
  Comment: Neither The Joint Commission Standard of Eating Disorders Care, nor the following sources used in the development of The Joint Commission's Standards mention or recommend metabolic testing or body composition devices.

  The following sources were used as references in the development of the eating disorders standards The Joint Commission, Eating Disorders Standards for Behavioral Health Care, 2016. Page 26-42.

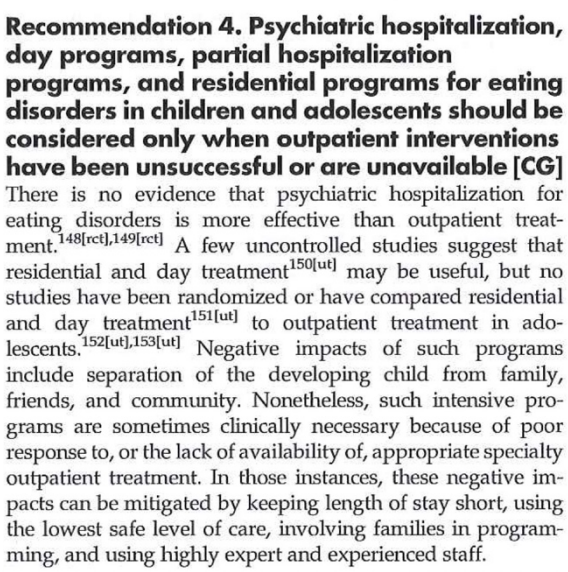
  - Practice Guideline for the Treatment of Patients with Eating Disorders, Third Edition. Arlington, Virginia: American Psychiatric Association, 2010 (graded level of evidence). (Accessed June 14, 2016).

A new edition of the APA Practice Guideline is in press, DRAFT February 28, 2022 NOT FOR CITATION https://www.psychiatry.org/File%20Library/Psychiatrists/Practice/Clinical%20Practice%20Guidelines/APA-Draft-Practice-Guidelines-Eating-Disorders.pdf

- Lock J, et al. Practice Parameter for the Assessment and Treatment of Children and Adolescents with Eating Disorders, *Journal of the American Academy of Child and Adolescent Psychiatry*, 2015 May;54(5):412-25 (graded level of evidence). (Accessed June 14, 2016).



In those patients in whom there is evidence of malnutrition or purging behaviors, initial laboratory testing typically includes a complete blood count, chemistry profile including electrolytes, blood urea nitrogen, creatinine, glucose, and liver functions including aspartate aminotransferase (AST) and alanine aminotransferase (ALT). These tests also can be used to monitor treatment. A thyroid-stimulating hormone (TSH) test should be ordered to rule out underlying thyroid dysfunction. Further blood testing should include measuring calcium, magnesium, phosphate, total protein, albumin, erythrocyte sedimentation rate (ESR), and amylase (as some studies suggest that elevations of amylase provide evidence that the patient is vomiting), B_{12}, and lipid profiles; in females, luteinizing hormone (LH), follicle-stimulating hormone (FSH), and estradiol levels should also be tested. If indicated, a pregnancy test using β–human chorionic gonadotropin (B-hCG) should also be considered to evaluate amenorrhea. Electrocardiograms are often necessary to further evaluate bradycardia and risk of cardiac arrhythmias. Dual-energy x-ray absorptiometry (DEXA) of bone should initially be conducted in females with amenorrhea lasting more than 6 months and yearly if amenorrhea persists.[140] All males with significant weight loss should also have a DEXA scan. Results of these data provide patients and families with guidance about the clinical impact of starvation on physical health and growth. Over time, improvements in these physical health parameters can help benchmark clinical progress. For example, for females with AN, normalization of estrogen levels can be a marker of healthy weight. At the same time, in more chronically ill patients with eating disorders, there can be a normalization of laboratory values that can suggest better health than is present.



Recommendation 4. Psychiatric hospitalization, day programs, partial hospitalization programs, and residential programs for eating disorders in children and adolescents should be considered only when outpatient interventions have been unsuccessful or are unavailable [CG]

There is no evidence that psychiatric hospitalization for eating disorders is more effective than outpatient treatment.[148[rct],149[rct]] A few uncontrolled studies suggest that residential and day treatment[150[ut]] may be useful, but no studies have been randomized or have compared residential and day treatment[151[ut]] to outpatient treatment in adolescents.[152[ut],153[ut]] Negative impacts of such programs include separation of the developing child from family, friends, and community. Nonetheless, such intensive programs are sometimes clinically necessary because of poor response to, or the lack of availability of, appropriate specialty outpatient treatment. In those instances, these negative impacts can be mitigated by keeping length of stay short, using the lowest safe level of care, involving families in programming, and using highly expert and experienced staff.

- Eating Disorders: Critical Points for Early Recognition and Medical Risk Management in the Care of Individuals with Eating Disorders, Second Edition. Deerfield, Illinois: Academy for Eating Disorders, 2012. (Accessed June 14, 2016)

Latest Edition: Academy of Eating Disorders in its Medical Care Standards Committee in its Eating Disorders: A Guide to Medical Care, Fourth Edition, (2021).

Submission does include The Joint Commission, Eating Disorders Standards for Behavioral

ResptoQ005 Resubmitted GMCB Standard Financial Tables (not including as contains only financial tables).

20220405_ResptoQ006.pdf (vermont.gov)

- Footnotes 1-12 (Believe these are all duplicative from articles included in Application. They used much of the same information included in the Application in their 11-page submission to Vermont Medicaid).

20220413_ResptoQ007.pdf (vermont.gov)

- Devices: Response to Q 2, 3, 4.
- No footnotes.

Q2

2. Specify the frequency of use and the justification that supports the frequency of use for the Metabolic Testing Device and for the Body Composition Analysis Testing Device for participants in the adult PHP program, the adult IOP program and the adolescent IOP program. Please address concerns that measurements can be a "triggering" event for a participant with an eating disorder and explain how the Kahm Clinic will recognize and minimize such distress if encountered with participants in the PHP and IOP programs.

Comment: Being exposed to weight checks, which are standard in treatment for eating disorders is difficult for patients, but serves to help them become more invulnerable and accepting of this basic health measure that is a standard component of general health care. Because metabolic testing and body composition analysis testing is unique to the Kahm Clinic, patients I have seen who have had treatment at Kahm are either traumatized or confused or feel dependent on the Kahm testing methods to feel comfortable. Not be told the "numbers" (results of device testing or weight checks) does not protect patients from obsessing about them. Of note, the evidence-based treatments of Cognitive Behavior Therapy (CBT) (Waller & Mountford, 2015) and Family Based Therapy (FBT) (Lock & Le Grange, 2019) both use open weighing. These are the treatments that have the best treatment outcomes for eating disorders. In fact, FBT is the type of treatment with the most support for adolescents with anorexia nervosa and weekly, open weighing is a non-negotiable part of FBT treatment.

Waller, G., & Mountford, V. A. (2015). Weighing patients within cognitive-behavioural therapy for eating disorders: how, when and why. Behaviour Research and Therapy, 70, 1-10.
Lock, J., & Le Grange, D. (2019). Family-based treatment: Where are we and where should we be going to improve recovery in child and adolescent eating disorders. International Journal of Eating Disorders, 52(4), 481-487.

Q3

3. Given that the Metabolic Testing device and the Body Composition Analysis device are not widely used in the treatment of eating disorders, explain in more detail the specific information generated by each device, how that specific information will be applied and how it improves quality and the informs the course of treatment for adults and adolescents in the IOP and PHP programs, and whether such information is shared with participants and their families. To the extent possible, provide objective standards that professionals use to interpret and apply the information and data generated by each device and medical resources used to inform those standards.

Comment: As the response to this question in the Kahm application is indicative of their approach, I will respond to their answers to Q3 by paragraph.

The specific information given by the machines are listed in the answer to a. of the first question of the second round of questions. This information is used by the dietitians to determine if the patient needs a meal plan increase or if their current meal plan is appropriate. For example, based on NHANES data, the normal range for a 20yo female's muscle mass begins at 42.4lb or above. If a client comes in and has a muscle mass of 38.9lb, it indicates that the body is using muscle as a source of fuel due to not being fed enough calories. As a result, the dietitian will know to increase the patient's meal plan. It would only be once the patient's muscle mass reaches 42.4lb or above that we know the person is healed internally. The Body Composition Analysis results will not be shared with patients or their families, it is solely used as a clinical tool to provide the best care possible. The objective standards for the Metabolic Test come from the Harris-Benedict Equation which is the industry standard for calculation of metabolic rate. The body composition analysis standards are based off the National Health and Nutrition Examination Survey (NHANES) through the CDC.

On the one hand, we use the "objective standards" routinely used in the industry, namely, NHANES and the Harris-Benedict Equation to determine "acceptable" ranges for the data points. On the other hand, the ultimate "objective standard," is the empirical data from the patient's own body. If the Harris Benedict Equation predicts that someone's RMR should be 1300, but that person's actual RMR is 600, then our dieticians know how to fuel that patient until their metabolism is within a healthy range.

Comment: Contrary to what is stated above in the Kalm application, NHANES and Harris-Benedict Equation are not used in evidenced-based treatment of eating disorders. There is no evidence that NHANES data on expected muscle mass ranges in should be used in the treatment of eating disorders to prescribe calorie levels or indicate "the person is healed internally." Neither is there any evidence that calculating REE from one of the standard equations such as the Harris-Benedict Equation or from available metabolic testing devices is clinically useful in designing

weight gain food plans (Kochavi et al., 2020). Evidence-based treatment bases calorie levels on whether the patient is gaining weight as expected (Haynos et al., 2016; Bargiacchi et al., 2019;Peebles et al., 2017; Garber et al., 2021).

Kochavi, B., Mendelowitsch, S., Enoch-Levy, A., Yaroslavsky, A., Toledano, A., Modan-Moses, D., & Stein, D. (2020). Resting energy expenditure in acutely ill and stabilized patients with anorexia nervosa and bulimia nervosa. International Journal of Eating Disorders, 53(9), 1460-1468.
Haynos, A. F., Snipes, C., Guarda, A., Mayer, L. E., & Attia, E. (2016). Comparison of standardized versus individualized caloric prescriptions in the nutritional rehabilitation of inpatients with anorexia nervosa. International Journal of Eating Disorders, 49(1), 50-58.
Bargiacchi, A., Clarke, J., Paulsen, A., & Leger, J. (2019). Refeeding in anorexia nervosa. European journal of pediatrics, 178(3), 413-422.
Peebles, R., Lesser, A., Park, C. C., Heckert, K., Timko, C. A., Lantzouni, E., ... & Weaver, L. (2017). Outcomes of an inpatient medical nutritional rehabilitation protocol in children and adolescents with eating disorders. Journal of eating disorders, 5(1), 1-14.
Garber, A. K., Cheng, J., Accurso, E. C., Adams, S. H., Buckelew, S. M., Kapphahn, C. J., ... & Golden, N. H. (2021). Short-term outcomes of the study of refeeding to optimize inpatient gains for patients with anorexia nervosa: a multicenter randomized clinical trial. JAMA pediatrics, 175(1), 19-27.

This is how it works with all data points listed in the answer to a. of the first question of the second round of questions. We have ranges based on large studies which are widely used. Because of these we know where the patient should be, and then because of the machines, we know where they actually are. The dietitian's job, in part, is to get them from where they are to an acceptable range. It is far more "objective" than what other dietitians are doing in standard treatments settings where they do not get the benefit of the machines. It is no different than, for instance, a pediatrician worrying about a child because she is too low on the height and weight charts. Pediatricians have acceptable ranges based on large widely used data sets; then they weigh and measure their patient's height, and they compare the actual empirical numbers to the acceptable ranges based on large population studies.

Comment: The Kahm application in answer to a. of the first question of the second round of questions did not give references for the data point ranges they use. It is unclear that this "objective" approach is better than standard treatment which is based on the individual's weight progression towards their pre-morbid weight or growth curve for child and adolescent patient and not "acceptable ranges based on large population studies" (Lebow et al., 2018; Golden et al., 2015).

Lebow, J., Sim, L. A., & Accurso, E. C. (2018). Is there clinical consensus in defining weight restoration for adolescents with anorexia nervosa?. Eating disorders, 26(3), 270-277.

Golden, N., Katzman, D., Sawyer, S., Ornstein, R., Rome, E., Garber, A., ... Kreipe, R. (2015). Update on the medical management of eating disorders in adolescents. Journal of Adolescent Health, 56 (4), 370 – 375.

For an answer as to how this would look in the treatment setting, please revisit our hypothetical cases in our response to the second question of the fourth round of questions. As for the part of this question about how this specific information will be used in IOP/PHP treatment, that is impossible to answer in the way the question is asked. Consider the PHP schedule in which a large percentage of the week is consumed by group therapies of various sorts. Can we tie an improvement in lean mass from the body composition analysis machine to a specific improvement in say CBT skills group rather than a body image group? No, of course not. This part of the question seems to us to be a rephrasing of b. of question 1 of the second round of questions. And I will repeat my answer to that question here….."Our dieticians use these medical machines as tools to help to cure malnutrition."

Comment: These machines are unnecessary to curing malnutrition in eating disorder patients and may cause dependence on machines that are not available in any other treatment milieu.

Q4

4. **Provide a detailed description of your contacts with Vermont Medicaid, the dates of contact, and the content of what was discussed. Provide copies of all documents you submitted to Vermont Medicaid. This must include requests made for reimbursement rates and codes for all services and the use of the two devices in both the adult PHP and the adult and adolescent IOP programs and specify whether the rates you requested included or excluded the charges per appointment or per week for both the Metabolic Testing device and the Body Composition Analysis device. Specify the frequency of use per patient for the Metabolic Testing device and the Body Composition Analysis device and whether that frequency of use is covered in the Medicaid rates you have negotiated with Vermont Medicaid. If not, please explain why the charges for the two devices were not included in the requested Medicaid rate. Provide a copy of signed letter of agreement with the Department of Vermont Health Access for the provision of services to Medicaid Members.**

Comment: The concern here is the use and frequency of use of the Metabolic Testing device and the Body Composition Analysis device as describe in previous comments. Furthermore, the Kahm application does not mention having a protocol for obtaining bodyweight measurements which is considered an established integral component of care for eating disordered patients, particularly for those diagnosed with anorexia nervosa (Kelly-Weeder et al., 2018; American Psychiatric Association, 2006).

Kelly-Weeder, S., Kells, M., Jennings, K., Dunne, J., & Wolfe, B. (2018). Procedures and Protocols for Weight Assessment During Acute Illness in Individuals With Anorexia Nervosa: A National Survey. Journal of the American Psychiatric Nurses Association, 24(3), 241–246. https://doi.org/10.1177/1078390317717790

American Psychiatric Association. Practice guidelines for the treatment of patients with eating disorders. 3. Arlington, VA: Author; 2006