February 21, 2023

Dr. Juan Schaening
First Coast Contractor Medical Director
Novitas Solutions
2020 Technology Pkwy
Suite 100
Mechanicsburg, PA 17050

Dear Dr. Schaening:

We write to express disappointment in the process for the Multi-Jurisdictional Contractor Advisory Committee (CAC) Meeting on Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) for Non-implantable Devices on February 28, 2023. Given the enormous power the Local Coverage Decision (LCD) process has over access to services and technologies by Medicare patients, we urge you to consider our recommendations for modifications. Our top concerns are the absence of important studies from the bibliography, the brevity of scheduled discussion, the combination of RPM and RTM into one meeting, whether the Medicare Administrative Contractors understand how health care providers offering RPM and RTM services operate to deliver high-quality care, and the absence of certain clinical conditions and disease states from consideration.

Pursuant to Section 4009 of H.R. 34-21st Century Cures Act (Public Law No: 114-255), the Local Coverage Determination process was changed to "help to increase transparency, clarity, consistency, reduce provider burden and enhance public relations while retaining the ability to be responsive to local clinical and coverage policy concerns." [1] These changes are reflected in Chapter 13 of the Medicare Program Integrity Manual which recognizes that:

> "…advice rendered by the CAC is most useful when it results from a process of **full scientific inquiry and thoughtful discussion** with careful framing of recommendations and clear identification of the basis of those recommendations…. The CAC is used to supplement the MAC's internal expertise and to ensure an **unbiased and contemporary consideration of 'state of the art' technology and science**."[2]

We are concerned that advice rendered by the CAC in this instance will not be the result of a full scientific inquiry, nor will it help ensure unbiased or contemporary consideration of state of the art technology and science. The ability to utilize remote patient monitoring (whether RPM or RTM) in managing patients post-hospitalization, and those patients with ongoing chronic disease is essential to better health outcomes. RPM and RTM provides better patient compliance and improved ability for physicians to manage care outside of the institution. Given the importance of these new technologies, we urge you to consider the evidence more comprehensively and allow for more time to digest and discuss the implications of the findings.

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[1] MLN Matters, Local Coverage Determinations, Effective October 3, 2018 (available at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10901.pdf).

[2] Medicare Program Integrity Manual Chapter 13, February 12, 2019 (available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c13.pdf)

The bibliography is missing at least 45 credible studies, including studies from some of the most well-known physicians using RPM. We understand that individual Subject Matter Experts (SMEs) can submit studies, but these will not be listed for review by all of the volunteer SMEs nor the MAC Committee and it is unclear by the agenda whether additionally submitted studies will only be accepted if they pertain to a condition not already covered by other literature in the bibliography. We urge you to re-issue the list with a more comprehensive review of the literature, including the resources attached to this letter.

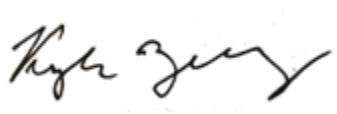
The allocated meeting time is far too short for a fulsome discussion of the topic, especially with RPM and RTM combined into one meeting. RPM and RTM are very different services, each of which deserve their own deliberation. You have assembled a group of SMEs who have on-the-ground experience and important insights into the use of these technologies, and you have asked them in pre-meeting questions to share that experience. However, you only allow for seventy-five minutes on the agenda for discussion, which is not enough time for meaningful evidentiary presentation and deliberation. These SMEs are meant to provide important education to CAC members about the use of RPM and RTM and put the evidence in context. They must be allowed to share those insights in a meaningful way. Further, we suggest that you allocated time for an introduction by experts with "on the ground" experience with remote monitoring on how these monitoring technologies are currently being deployed to improve care and the payment models which support them.

Finally, we urge you to broaden the evidence related to the wide range of conditions for which RPM/RTM are appropriate and rely upon the impressive SME expertise collected to determine the most appropriate studies for review. There is a broad range of chronic conditions for which utilizing RPM and RTM are appropriate, and limiting the evidentiary review indicates you are considering limiting an LCD to only the conditions considered. This would leave clinicians currently using RPM outside of cardiology with no feasible way to continue.

In conclusion, we believe that an inclusive discussion with CAC members on RPM and RTM experiences and efficacy, consistent with the above, will have immense benefit to MACs, other policymakers, and the public. We request your partnership in advancing policy that will bring the benefits of digital health technologies, including RPM and RTM, to American patients equitably.

Thank you for your consideration.

Sincerely,



Kyle Zebley
Senior Vice President, Public Policy
American Telemedicine Association

Chris Adamec
Vice President
Alliance for Connected Care

Attachment 1 – RPM Studies

Ambrosy AP, Fonarow GC, Butler J, et al.	The Global Health and Economic Burden of Hospitalizations for Heart Failure
Mills KT, Bundy JD, Kelly TN, et al.	Global Disparities of hypertension Prevalence and control
Forouzanfar MH, Liu P, Roth GA, et al.	Global Burden of Hypertension and Systolic Blood Pressure of at Least 110 to 115 mm Hg, 1990-2015
Dieleman JL, Baral R, Birger M, et al.	US Spending on Personal Health Care and Public Health, 1996-2013
Fragasso G.	Editorial Commentary: Drug dosing optimization in heart failure: Need of a multidimensional approach (and skilled heart failure specialists)
Adamson PB.	Pathophysiology of the Transition From Chronic Compensated and Acute Decompensated Heart Failure: New Insights From Continuous Monitoring Devices
Gheorghiade M, Albert NM, Curtis AB, et al.	Medication Dosing in Outpatients With Heart Failure After Implementation of a Practice-Based Performance Improvement Intervention: Findings From IMPROVE HF
Whelton PK, Carey RM, Aronow WS, et al.	ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults
Bundy JD, Mills KT, Chen J, Li C, Greenland P, He J.	Estimating the Association of the 2017 and 2014 Hypertension Guidelines With Cardiovascular Events and Deaths in US Adults
Olufade T, Zhou S, Anzalone D, et al.	Initiation Patterns of Statins in the 2 Years After Release of the 2013 American College of Cardiology/American Heart Association (ACC/AHA) Cholesterol Management Guideline in a Large US Health Plan
CHF	
Mebazaa A, Davison B, Chioncel O, et al.	Safety, tolerability and efficacy of up-titration of guideline-directed medical therapies for acute heart failure (STRONG-HF): a multinational, open-label, randomised, trial. Lancet. 2022;400(10367):1938-1952.
Koehler F, Koehler K, Deckwart O, et al.	Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. Lancet. 2018;392(10152):1047-1057.
Bekfani T, Fudim M, Cleland JGF, et al.	A current and future outlook on upcoming technologies in remote monitoring of patients with heart failure. Eur J Heart Fail. 2021;23(1):175-185
Maeng DD, Starr AE, Tomcavage JF, Sciandra J, Salek D, Griffith D.	Can telemonitoring reduce hospitalization and cost of care? A health plan's experience in managing patients with heart failure. Popul Health Manag. 2014;17(6):340-344.
Desai AS, Maclean T, Blood AJ, et al.	Remote Optimization of Guideline-Directed Medical Therapy in Patients With Heart Failure With Reduced Ejection Fraction [published correction appears in JAMA Cardiol. 2021 Apr 1;6(4):485]. JAMA Cardiol. 2020;5(12):1430-1434
Böhm M, Drexler H, Oswald H, et al.	Efficacy of telemedicine for the management of cardiovascular disease: a systematic review and meta-analysis. Lancet Digit Health. 2022;4(9):e676-e691.
Hindricks G, Taborsky M, Glikson M, et al.	Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial. Lancet. 2014;384(9943):583-590.
Cleland JG, Louis AA, Rigby AS, Janssens U, Balk AH;	TEN-HMS Investigators. Noninvasive home telemonitoring for patients with heart failure at high risk of recurrent admission and

	death: the Trans-European Network-Home-Care Management System **(TEN-HMS)** study. J Am Coll Cardiol. 2005;45(10):1654-1664.
Abraham WT, Stevenson LW, Bourge RC	Sustained efficacy of pulmonary artery pressure to guide adjustment of chronic heart failure therapy: complete follow-up results from the **CHAMPION** randomised trial. Lancet. 2016;387(10017):453-461.
Fonarow GC, Yancy CW, Hernandez AF, Peterson ED, Spertus JA, Heidenreich PA.	Potential impact of optimal implementation of evidence-based heart failure therapies on mortality. Am Heart J. 2011;161(6):1024-30
Greene SJ, Butler J, Albert NM, et al.	Medical Therapy for Heart Failure With Reduced Ejection Fraction: The CHAMP-HF Registry. J Am Coll Cardiol. 2018;72(4):351-366
Savarese G, Kishi T, Vardeny O, et al.	Heart Failure Drug Treatment-Inertia, Titration, and Discontinuation: A Multinational Observational Study (EVOLUTION HF). JACC Heart Fail. 2023;11(1):1-14.
Bottle A, Kim D, Aylin P, Cowie MR, Majeed A, Hayhoe B.	Routes to diagnosis of heart failure: observational study using linked data in England. Heart. 2018;104(7):600-605.
Lawson CA, Zaccardi F, Squire I, et al.	20-year trends in cause-specific heart failure outcomes by sex, socioeconomic status, and place of diagnosis: a population-based study. Lancet Public Health. 2019;4(8):e406-e420.
Sharma A, Verma S, Bhatt DL, et al.	Optimizing Foundational Therapies in Patients With HFrEF: How Do We Translate These Findings Into Clinical Care?. JACC Basic Transl Sci. 2022;7(5):504-517.
Ong MK, Romano PS, Edgington S, et al.	Effectiveness of Remote Patient Monitoring After Discharge of Hospitalized Patients With Heart Failure: The Better Effectiveness After Transition -- Heart Failure (**BEAT-HF**) Randomized Clinical Trial [published correction appears in JAMA Intern Med. 2016 Apr;176(4):568] [published correction appears in JAMA Intern Med. 2016 Jun 1;176(6):871]. JAMA Intern Med.
Zaman S, Zaman SS, Scholtes T, et al.	The mortality risk of deferring optimal medical therapy in heart failure: a systematic comparison against norms for surgical consent and patient information leaflets. Eur J Heart Fail. 2017;19(11):1401-1409.
Ledwidge MT, O'Connell E, Gallagher J, et al.	Cost-effectiveness of natriuretic peptide-based screening and collaborative care: a report from the STOP-HF (St Vincent's Screening TO Prevent Heart Failure) study. Eur J Heart Fail. 2015;17(7):672-679.
Morgan JM, Kitt S, Gill J, et al.	Remote management of heart failure using implantable electronic devices. Eur Heart J. 2017;38(30):2352-2360.
Rahimi K, Nazarzadeh M, Pinho-Gomes AC, et al.	Home monitoring with technology-supported management in chronic heart failure: a randomised trial. Heart. 2020;106(20):1573-1578.
Kotooka N, Kitakaze M, Nagashima K, et al.	The first multicenter, randomized, controlled trial of home telemonitoring for Japanese patients with heart failure: home telemonitoring study for patients with heart failure (HOMES-HF). Heart Vessels. 2018;33(8):866-876.
HTN	
Margolis KL, Asche SE, Bergdall AR, et al.	Effect of home blood pressure telemonitoring and pharmacist management on blood pressure control: a cluster randomized clinical trial. JAMA. 2013;310(1):46-56.
Blood AJ, Cannon CP, Gordon WJ, et al.	Results of a Remotely Delivered Hypertension and Lipid Program in More Than 10 000 Patients Across a Diverse Health Care Network

	[published correction appears in JAMA Cardiol. 2022 Nov 30;:]. JAMA Cardiol. 2023;8(1):12-21.
Fernando ME, Seng L, Drovandi A, Crowley BJ, Golledge J.	Effectiveness of Remotely Delivered Interventions to Simultaneously Optimize Management of Hypertension, Hyperglycemia and Dyslipidemia in People With Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials [published correction appears in Front Endocrinol (Lausanne). 2022 May 09;13:916377]. Front Endocrinol
Mills KT, Obst KM, Shen W, et al.	Comparative Effectiveness of Implementation Strategies for Blood Pressure Control in Hypertensive Patients: A Systematic Review and Meta-analysis. Ann Intern Med. 2018;168(2):110-120
Margolis KL, Asche SE, Dehmer SP, et al.	Long-term Outcomes of the Effects of Home Blood Pressure Telemonitoring and Pharmacist Management on Blood Pressure Among Adults With Uncontrolled Hypertension: Follow-up of a Cluster Randomized Clinical Trial. JAMA Netw Open. 2018;1(5):e181617.
Margolis KL, Dehmer SP, Sperl-Hillen J, et al.	Cardiovascular Events and Costs With Home Blood Pressure Telemonitoring and Pharmacist Management for Uncontrolled Hypertension. Hypertension. 2020;76(4):1097-1103.
T2DM	
Su D, Zhou J, Kelley MS, et al.	Does telemedicine improve treatment outcomes for diabetes? A meta-analysis of results from 55 randomized controlled trials. Diabetes Res Clin Pract. 2016;116:136-148.
Zhai YK, Zhu WJ, Cai YL, Sun DX, Zhao J.	Clinical- and cost-effectiveness of telemedicine in type 2 diabetes mellitus: a systematic review and meta-analysis. Medicine (Baltimore). 2014;93(28):e312.
Di Molfetta S, Patruno P, Cormio S, et al.	A telemedicine-based approach with real-time transmission of blood glucose data improves metabolic control in insulin-treated diabetes: the DIAMONDS randomized clinical trial. J Endocrinol Invest. 2022;45(9):1663-1671.
Fernando ME, Seng L, Drovandi A, Crowley BJ, Golledge J.	Effectiveness of Remotely Delivered Interventions to Simultaneously Optimize Management of Hypertension, Hyperglycemia and Dyslipidemia in People With Diabetes: A Systematic Review and Meta-Analysis of Randomized Controlled Trials [published correction appears in Front Endocrinol (Lausanne). 2022 May 09;13:916377]. Front Endocrinol
Yin W, Liu Y, Hu H, Sun J, Liu Y, Wang Z.	Telemedicine management of type 2 diabetes mellitus in obese and overweight young and middle-aged patients during COVID-19 outbreak: A single-center, prospective, randomized control study. PLoS One. 2022;17(9):e0275251
Lee PA, Greenfield G, Pappas Y.	The impact of telehealth remote patient monitoring on glycemic control in type 2 diabetes: a systematic review and meta-analysis of systematic reviews of randomised controlled trials. BMC Health Serv Res. 2018;18(1):495. Published 2018 Jun 26.