September 11, 2021

The Honorable Xavier Becerra, Secretary
The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016.

Submitted electronically via www.regulations.gov

RE: Comments to CY 2022 Proposed Medicare Physician Fee Schedule (CMS-1751-P)

- **Section II.E., Valuation of Specific Codes**

Dear Secretary Becerra and Administrator Brooks-LaSure:

I am the Chief Executive Officer of Adherium Limited ("Adherium"), an international respiratory ehealth company focused on medication adherence, remote patient monitoring, and data management for patients, payers, and providers. Our smart inhaler sensor technology and software platform provide real- time feedback on patients' use of inhaled medications for respiratory conditions such as COPD and asthma. We applaud CMS' continued recognition of the value of remote monitoring and other digital health solutions through proposed reimbursement for Remote Therapeutic Monitoring ("RTM") in the proposed revisions to the 2022 Medicare Physician Fee Schedule (the "Proposed Rule").

Adherium manufactures ten FDA-cleared, Bluetooth-enabled medical devices that wrap around patient inhalers and automatically collect and transmit patient medication usage, adherence, technique, and inhalation data, including peak inhalation flow to the Adherium Hailie® app. Patients who have used our solution have experienced a reduction in severity and frequency of exacerbations[1], a reduction in oral steroid use and less hospital admissions[2], and improved outcomes and quality of life[3].

I want to take this opportunity to provide feedback on the Proposed Rule. Not only do we believe that our comments will benefit Medicare beneficiaries, and we also understand the immense impact the Medicare Physician Fee Schedule can have on reimbursement policies set by commercial payors, state Medicaid programs, and other health insurance programs that directly affect non-Medicare beneficiaries. We encourage CMS to continue expansion and support for medication adherence monitoring and other forms of remote patient monitoring to benefit Medicare patients long past the end of the COVID-19 PHE.

During the pandemic, this expansion has proven to be vital in improving and maintaining the health of the elderly and those at most risk with comorbidities without the need to utilize and burden other elements

[1] Foster JM, Smith L, Usherwood T, Sawyer SM, Reddel HK. Inhaler reminders improve adherence with controller treatment in primary care patients with asthma. J Allergy Clin Immunol. 2014;134(6):1260-1268.e3

[2] Morton RW, Elphick HE, Rigby AS, Daw WJ, King DA, Smith LJ, Everard ML. STAAR: a randomised controlled trial of electronic adherence monitoring with reminder alarms and feedback to improve clinical outcomes for children with asthma. Thorax Online First. 2016;0:1-8

[3] Chan AHY, Stewart AWS, Harrison J, Camargo C, Black PN, Mitchell EA. The effect of an electronic monitoring device with audiovisual reminder function on adherence to inhaled corticosteroids and school attendance in children with asthma: a randomised controlled trial. Lancet Respir Med. 2015;3:210-219

of the healthcare system. The COVID-19 pandemic has put an incredible strain on the healthcare system and has created a respiratory state of emergency for patients with severe respiratory conditions. Digital health and remote monitoring have made it possible to keep these patients safer in their homes by avoiding unnecessary in-person office and emergency room visits, improving engagement and overall health, and providing more direct communication between patients and their providers. The healthcare industry has reached an inflection point and there is no going back to a system that relies almost entirely on in-person visits following the end of the PHE. Remote monitoring and telehealth are quickly becoming the new standard of care. Continued expansion of telehealth and remote monitoring services, especially for products in the respiratory diseases category, is essential for reducing health care disparities and inequities among ALL patients, especially the socioeconomically disadvantaged, elderly, and people of color who are particularly at risk.

Furthermore, as the pandemic becomes endemic and people who are infected and recover from COVID-19 with lingering health problems following the acute phase of the illness (sometimes known as "long haulers") will require continuous care and treatment. Going forward, remote monitoring and telehealth are essential and indispensable tools for our healthcare system to survive in the future.

Summary of Key Points

- CMS should clarify that both RTM and RPM can be billed concurrently so long as the requirements for each are met separately.

- CMS should clarify that the RTM CPT codes, as currently proposed, DO allow therapists and other QHCPs who can independently bill Medicare to order and bill for RTM. CMS should also clarify that pharmacists are QHCPs for purposes of RTM.

- CMS should align the coding constructs for RPM and RTM by finalizing, on an interim basis, a set of additional HCPCS G-codes for RTM that mirrors the current code descriptors for the RPM E/M CPT code set and designate those codes as "care management services".

- CMS should restrict the RTM code sets to the same minimum thresholds as RPM for a minimum 16 days monitored within a 30-day period.

- CMS should allow for 989X2 and 989X3 to be billed once per device supplied to the patient to track "total adherence."

- CMS should require automated data reporting and should NOT allow self-reported data for medication adherence monitoring.

- CMS should recategorize Software as a Medical Device (SaMD) and ongoing maintenance of SaMD as direct practice expenses (dPE).

Section II.E.4(37), Remote Therapeutic Monitoring (CPT Codes 989X1, 989X2, 989X3, 989X4, and 989X5)

We applaud CMS for introducing the Remote Therapeutic Monitoring ("RTM") codes and recognizing the desire of stakeholders to: (1) expand the types of patient data that can be captured and utilized for remote monitoring and care management, and (2) expand the types of practitioners who can order and bill for

remote monitoring of patient data and associated care management services. As CMS notes in the Proposed Rule, the RTM codes present certain barriers to ensuring the codes can be used as intended. Below are our suggestions for how CMS can remedy these issues in the final 2022 MPFS.

The RTM codes are described as follows in the Proposed Rule:

- **CPT code 989X4** - *Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes*
- **CPT code 989X5** - *Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)*
- **CPT code 989X1** - *Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment*
- **CPT code 989X2** - *Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor respiratory system, each 30 days*
- **CPT code 989X3** - *Remote therapeutic monitoring (e.g., respiratory system status, musculoskeletal system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days*

a. CMS should clarify that RTM and RPM can be billed concurrently so long as the requirements for each are met separately.

Like Chronic Care Management ("CCM"), Behavioral Health Integration ("BHI"), and other care management services, RTM represents a distinct service from RPM. Some of Adherium's devices collect both physiologic and therapeutic metrics and we know that there are some conditions, such as asthma and COPD, that require monitoring of both to properly assess a patient's health status. We also know that in some cases, one provider will focus on monitoring physiologic metrics while another provider monitors therapeutic data.

For example, a patient with COPD can benefit from a respiratory therapist monitoring therapeutic data (such as adherence, inhaler technique and therapy response) while the patient's physician will monitor the patient's pulmonary function (via inspiratory flow data and blood oxygen levels). In other instances, a physician may monitor adherence and inspiratory flow in asthmatic patients to ensure they are using their prescribed inhalers as directed and to assess the efficacy of the specific inhaled medication(s) prescribed. Each data point likely requires distinct time spent, treatment decisions, and patient engagement. As such, providers should be allowed to bill for RTM and RPM, as applicable, when both physiologic and therapeutic measures are being monitored for the same patient to appropriately capture the distinct services the patient receives. Otherwise, providers will be incentivized to choose to monitor just one category of data even when their patient(s) may benefit from both. **CMS should clarify that both RTM and RPM can be billed concurrently so long as the requirements for each are met separately.**

b. CMS should clarify that the RTM CPT codes, as currently proposed, DO allow therapists and other QHCPs who can independently bill Medicare to order and bill for RTM.

CMS correctly notes in the Proposed Rule that the RTM codes created by the CPT Committee are located in the Medicine (often referred to as the "general medicine") section of the CPT manual. However, codes in the general medicine section are available to Qualified Health Care Practitioners ("QHCPs") who are not able to independently order and bill for Evaluation and Management ("E/M") services but who are properly qualified through "education, training, [and] licensure/regulation (when applicable)" to provide the services described by the codes. The RTM codes refer to "therapeutic monitoring", which CMS has described as monitoring pain, medication adherence, therapy adherence and response, musculoskeletal status, and respiratory status. Each of these categories represent data that physical therapists, occupational therapists, respiratory therapists, clinical psychologists, licensed clinical social workers, registered dieticians, and other practitioners are qualified to monitor. As such, these QHCPs are eligible to order and bill for RTM under the codes as currently proposed. **CMS should finalize these codes as proposed to clarify that QHCPs are eligible to bill them in the final rule.** This change is especially important for providers of health care to the rural, poor, elderly, and people of color that disproportionately suffer from these maladies.

Importantly, though, this means that the proposed RTM codes will NOT allow incident-to billing of clinical staff time under the general supervision of the billing practitioner.

Additionally, we urge CMS to align with the United States Department of Health and Human Services ("HHS") in recognizing that pharmacists may order certain therapeutics and recognize pharmacists as QHCPs for purposes of ordering and billing RTM. In the case of medication adherence, pharmacists are uniquely qualified to monitor and assess whether a patient is taking the appropriate dose of their medication at the right time and whether they are experiencing certain side effects that warrant a change. In many states pharmacists even have the authority to change a patient's dosage, further demonstrating that they are qualified to monitor and assess medication-related data. As such, **CMS should clarify in the final rule that pharmacists are QHCPs for purposes of billing the RTM codes when providing monitoring services within their scope of practice.**

c. CMS should align the coding constructs for RPM and RTM by finalizing, on an interim basis, a set of additional HCPCS G-codes for RTM that mirrors the current code descriptors for the RPM E/M CPT code set and designate those codes as "care management services."

The RTM professional service codes, as proposed, do not include clinical staff time in the code descriptors. Further, CMS rightfully points out in the Proposed Rule that only "care management services" allow clinical staff to provide services on an incident-to basis under the general supervision of the billing practitioner. This means that codes 989X4 and 989X5, as proposed, do not allow clinical staff time to count toward the 20-minute time requirement necessary to bill, nor can the codes be designated as "care management services." While we believe that CMS should finalize the RTM codes as proposed to sufficiently expand the provider types that can order and bill the codes, we believe that CMS should also create additional HCPCS G codes to allow for physicians and non-physician practitioners ("NPPs") to bill for system/condition agnostic device supply and patient set-up/education and to leverage clinical staff time on an incident-to basis. CMS should designate the RTM HCPCS G-code set as "care management services" to allow for general supervision.

CMS introduced the first standalone Remote Patient Monitoring code, CPT code 99091, in 2018. CPT code 99091 requires 30 minutes of physician or QHCP time in a 30-day period. CMS expected significant adoption and utilization of CPT Code 99091 as a means of identifying and intervening in patient problems early. However, low utilization data reflected physician and NPP feedback that they did not have capacity to spend 30 minutes of time per month interacting with each patient's data. This misunderstanding inadvertently and unfortunately excluded patients who stood to benefit from RPM. To remedy this issue, CMS and the CPT Committee acknowledged stakeholder feedback and introduced, in the 2019 MPFS, the much more practical set of RPM codes that are used more frequently today – CPT codes 99453, 99454, 99457 and, in 2020, 99458. CMS further designated these HCPCS G- codes as "care management services" to allow for general supervision of clinical staff.

CMS has requested suggestions from stakeholders for how to develop a coding structure in the 2022 MPFS Final Rule that allows for billing practitioners to leverage clinical staff under general supervision. We believe CMS can remedy these issues with a separate but parallel code set for RTM that more closely resembles RPM, as described below.

CMS should finalize, on an interim basis, an <u>additional HCPCS G-code set for RTM</u> with code descriptors as follows:

- *Remote therapeutic monitoring (e.g. system status, therapy adherence, therapy response); initial set-up and patient education on use of equipment* (system agnostic HCPCS G-code cross walked to CPT code 99453)

- *Remote therapeutic monitoring (e.g., system status, therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s), each 30 days* (system agnostic HCPCS G-code cross-walked to CPT Code 99454)

- *Remote therapeutic monitoring treatment management services,* ***clinical staff****/physician/other qualified healthcare professional time in a calendar month monitoring requiring at least one interactive communication with the patient/caregiver during the month; first 20 minutes* (cross walked to RPM CPT code 99457)

- *Remote therapeutic monitoring treatment management services,* ***clinical staff****/physician/other qualified healthcare professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the month; each additional 20 minutes* (cross walked to RPM CPT code 99458)

These HCPCS G-codes, if finalized, will allow for physicians and NPPs to leverage clinical staff time because the codes will include "clinical staff" time in the descriptors.

CMS has authority to create new codes in the final rule, as evidenced by its introduction of HCPCS code G2252 in the 2021 Final Rule. In CMS' proposed revisions to the 2021 Medicare Physician Fee Schedule ("2021 Proposed Rule"), CMS requested feedback from stakeholders regarding whether it should introduce reimbursement for virtual check-ins that require more time than provided for under HCPCS code G2012. In the 2021 Medicare Physician Fee Schedule Final Rule (the "2021 Rule"), CMS introduced for the first time and finalized HCPCS code G2252 on an interim basis in response to stakeholder feedback that such a code was needed. In the same fashion, **CMS should introduce and finalize these new RTM HCPCS G-codes on an interim basis to fill the gaps created by the currently proposed RTM CPT codes.**

Like RPM and other care management services, RTM involves establishing, implementing, revising, and monitoring according to a specific treatment plan for a patient. **As such, CMS should designate the HCPCS RTM G-codes as "care management services" to allow for general supervision of clinical staff.**

d. We urge CMS to restrict the RTM code sets to the same minimum thresholds as RPM for days monitored.

Although we are asking CMS to create, on an interim basis, final HCPCS G-codes cross walked to the RPM CPT codes, we urge CMS **to** require at least 16 days of data collection per 30-day period for the device supply and set-up codes.

e. We further urge CMS to allow for RTM device supply codes to be billed multiple times when multiple devices are provided to a patient to track "total adherence."

Respiratory care may involve prescribing multiple inhalers for multiple purposes to patients, all of which are necessary for complete patient management. For example, an asthma patient may require one or more maintenance inhaler(s) and a rescue inhaler. Those in most need of RTM services are the most expensive to the US healthcare system and suffer from multiple chronic diseases and comorbidities. This patient population is also prescribed numerous medications and require programs like RTM to increase adherence and improve patient outcomes. It is important that **all** inhalers being used by the patient are monitored and data is collected to track "total adherence" and provide comprehensive insights into possible over-medicating, possible under-medicating, and possible non-medicating to the provider. This means that for each inhaler provided to a patient, a patient will require a separate device to appropriately monitor their adherence. Each device carries distinct costs that likely will not be covered by only one billing of an associated device code, potentially leaving patients without the ability to monitor their use of all medications. As such, CMS should finalize in the Final Rule that all RTM device supply codes are billable per medically necessary *device* supplied to the patient.

f. CMS should require automated data reporting and should NOT allow self-reported data for medication adherence monitoring.

Practitioner experience and clinical evidence support the notion that monitoring therapeutic data and incorporating that data as part of care/treatment management services improves patient outcomes and reduces the overall cost of care.

By introducing the concept of RTM, CMS recognizes that there is an important category of patient data that does not necessarily fit the definition of "physiologic data" as described in the RPM code set. "Therapeutic data," which includes adherence measurements, and therapy response which often cannot be captured by using or wearing a device that automatically transmits data.

Patient self-reported data is widely recognized as having severe limitations. It can however be appropriate for capturing pain levels, activity, weight, Covid/influenza vaccine status, environmental conditions, quality of life, and mood, but as the consideration of Real World Data is expanding, the need for precise data has become essential. Therefore, **we do not believe that patient self-reported data alone is appropriate for monitoring medication adherence.** Studies show that patient self-reported adherence to

medication is not enough and needs to be additionally validated through other means to provide maximum benefit to patients[4,5].

Adherium's respiratory platform provides clinicians with access to a variety of patient centric data from connected devices including medication usage, adherence, and device connectivity, and in addition, insights into patient inhaler technique and their patterns of use. There is no need for patient self-reported data in this environment, as technology exists to collect it in a more accurate and clinically valid way.

In light of the above, CMS should not allow self-reported data for medication adherence monitoring.

g. CMS should recategorize Software, including Software as a Medical Device (SaMD), and ongoing maintenance of SaMD as direct practice expenses (dPE).

CMS notes in the Proposed Rule that it has traditionally "considered most computer software and associated analysis and licensing fees to be indirect costs tied to costs for associated hardware that is medical equipment." We believe this view of software is antiquated and does not align with innovation of available technology involved in patient care, particularly with respect to care management services like RPM and RTM. Importantly, CMS notes in the Proposed Rule that software typically requires little-to-no physical space compared to hardware equipment. However, the amount of physical space that SaMD occupies does not correlate to the cost a practice incurs for purchasing or maintaining it and many services defined by CPT and HCPCS codes would not exist without certain software inputs. Software carries additional costs that physical spaces do not, such as ongoing development, continuous updates, multiple interfaces and platforms, cloud storage, and blue-tooth, WiFi, and cellar connections. Plus, software requires additional customer service staff, technical support staff, and call center personnel to keep the service connected and operational. Further, the Food and Drug Administration is expanding its reach in regulating SaMD and CMS' outdated interpretation creates a bias against innovation and the role that this information can play in providing improved healthcare to the most disadvantaged beneficiaries.

In the case of RPM, for example, CMS requires that devices "automatically transmit" physiologic data to be reimbursable under CPT code 99454. Without software functions that facilitate automatic transmission and display the transmitted data, the automatic transmission requirement would not be possible, and providers would not have access to their patients' remotely collected data. The latter will also be true for RTM.

Importantly, for therapeutic measures like pain and mood for which there is no existing hardware that collects relevant data, software is the simplest and most efficient method of collecting the data. Without it, providers would need to use less efficient and less secure forms of communication (e.g., telephone, email, text message) to collect this information from patients. **Therefore, we urge CMS to recognize software (especially Software as a Medical Device (SaMD)) and ongoing maintenance of software as direct practice expenses (dPE).**

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[4] Neelima C. Tangirala, Rachel O'Conor, Michael S. Wolf, Juan P. Wisnivesky & Alex D. Federman (2020) Validity of the Medication Adherence Rating Scale for Adherence to Inhaled Corticosteroids among Older Adults with Asthma or Chronic Obstructive Pulmonary Disease, COPD: Journal of Chronic Obstructive Pulmonary Disease, 17:1, 74-80, DOI: 10.1080/15412555.2020.1712688

[5] Makhecha S, Chan A, Pearce C, et al. Novel electronic adherence monitoring devices in children with asthma: a mixed-methods study. BMJ Open Respiratory Research 2020;7:e000589. doi: 10.1136/bmjresp-2020-000589

Thank you for your consideration of our comments, and should you have any questions please do not hesitate to contact me.

Sincerely,

DocuSigned by:
Rick Legleiter
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Rick Legleiter, Chief Executive Officer, Adherium Limited