

August 27, 2018

The Honorable Seema Verma
Administrator
U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Calendar Year (CY) 2019 Home Health Prospective Payment System Rate Update and CY 2020 Case-Mix Adjustment Methodology Refinements; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; Home Infusion Therapy Requirements; and Training Requirements for Surveyors of National Accrediting Organizations (83 FR 32340)

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed CY 2019 Home Health Prospective Payment System Rate Update.

The Use of Remote Patient Monitoring Under the Medicare Home Health Benefit

The AMA strongly supports CMS' efforts to provide a pathway to clinical integration of virtual health care services. Such services expand the options available to physicians and the health care team to ensure that the right medical care is provided at the right time and in a patient centered manner. As a threshold matter, the AMA agrees that remote patient monitoring (RPM)¹ services are not "telehealth" services under the Medicare provisions of the Social Security Act. As a result, the AMA concurs that RPM services are not subject to the Social Security Act's section 1834(m) originating and geographic Medicare telehealth restrictions. The AMA also supports the proposal to permit the technical components of RPM as allowable administrative costs in a home health agency's cost report if remote patient monitoring is used by the home health agency to augment the care planning process. However, as discussed in greater detail below, the AMA strongly urges CMS to not establish a home health only CMS Healthcare Common Procedure Coding System (HCPCS) code for remote patient monitoring, but to instead provide for the use of the following two codes to accurately report the technical components of RPM services:

- Current Procedural Terminology (CPT) code 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).

¹ In the proposed CY2019 Medicare Physician Fee Schedule, CMS refers to remote patient monitoring that would apply to a number of conditions as chronic care remote physiologic monitoring. There are additional codes for remote monitoring that apply to specific conditions.

- CPT code 990X1 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).

The clinical evidence base in support of RPM services is substantial. The AMA established a [Digital Medicine Payment Advisory Group](#) (DMPAG) in 2017 comprised of national experts (primarily practicing physicians) in virtual health services in order to identify which virtual services and modalities have a sufficient clinical evidence base to support coding, coverage, and payment. Early deployments of RPM services took place in the early 1990s, but since 2009 the incidence of RPM has been increasing.² The DMPAG advisors evaluated the meta-analyses related to RPM services contained in the [Technical Brief Telehealth: Mapping the Evidence for Patient Outcomes from Systematic Reviews](#) (2016) conducted by the Agency for Healthcare Research & Quality. In addition, the DMPAG considered the summary of the meta-analysis conducted by the National Quality Forum (NQF) summarized in NQF's draft report [Creating a Framework to Support Measure Development for Telehealth](#) (July 2017), which included a review of RPM services. The DMPAG advisors also offered and considered peer reviewed literature in support of RPM services for a number of conditions. As summarized in Appendix A, there is extensive evidence that validates clinical efficacy of remote patient monitoring/management for chronic conditions (asthma, COPD, obesity, hypertension, diabetes, and congestive heart failure) and other follow-up care (post-surgical, cancer). There are a number of centers for medicine around the nation that incorporate RPM in the management of their patients with chronic conditions, including chronic kidney disease and heart failure. The Cleveland Clinic system alone provides outpatient RPM management for patients with chronic medical conditions and those who need management for anticoagulation, chronic kidney disease, congestive heart failure, anemia, and osteoporosis. A Cleveland Clinic published study describes benefits of RPM services based on a multicenter, randomized clinical trial that evaluated home-with clinic-based multidisciplinary management for post-acute heart failure patients.³ Additional literature demonstrating the clinical efficacy of RPM services include:

- A study where participants were given a device that uploaded blood glucose and blood pressure readings daily to a central server. The authors concluded that technology-assisted case management by a nurse with medication titration under physician supervision is efficacious in improving glycemic control in low-income rural adults with poorly controlled type 2 diabetes.⁴
- A study evaluating paired glucose testing and asynchronous data analysis in adults with type 2 diabetes. The authors found that an eHealth model incorporating a complete feedback loop with RPM and paired glucose testing with asynchronous data analysis significantly improved A1c levels compared to usual care. The study concluded that RPM may improve clinical outcomes, care coordination, engagement, and satisfaction.⁵

² Source: http://www.nahc.org/assets/1/7/10hc_stats.pdf

³ Gorodeski, EZ et al., Home-base care for heart failure: Cleveland Clinic's "Heart Care at Home" transitional care program, *Cleveland Clinic Journal of Medicine* 2013 January; 80(e-suppl 1):e-S20–e-S26)

⁴ Egede, LE et al. Randomized Controlled Trial of Technology-Assisted Case Management in Low Income Adults with Type 2 Diabetes, *Diabetes Technology & Therapeutics* 2017 June 5

⁵ Greenwood DA et al., Overcoming Clinical Inertia: A Randomized Clinical Trial of a Telehealth Remote Monitoring Intervention Using Paired Glucose Testing in Adults With Type 2 Diabetes, *J Med Internet Res* 2-015 Jul; 17(7): e178.

- A study assessing the feasibility, acceptability, and preliminary outcomes of a prototype medication and blood pressure self-management system for kidney transplant patients with uncontrolled hypertension. The finding concluded that the RPM intervention group exhibited significant improvements in medication adherence and significant reductions in clinic-measured systolic blood pressures.⁶
- A systemic review of English-language studies published in MEDLINE, The Cochrane Library, and the International Network of Agencies for Health Technology Assessment databases that presented results on the clinical effects of home RPM on patients with diabetes, asthma, heart failure, or hypertension. The paper assessed the research in those four chronic conditions, and identified critical success factors for home RPM programs. It demonstrates the broad use of home RPM devices.⁷

While the AMA supports efforts to increase the availability of RPM services for Medicare patients, the AMA does not support the proposed creation of a new home health only CMS HCPCS code for RPM that is described as follows:

the collection of physiologic data (for example, electrocardiograph (ECG), blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the home health agency.

The proposed code descriptor is problematic for two reasons. First, the above descriptor does not accurately describe all of the technical components that should be provided by the home health agency. We agree with the Agency that code(s) other than CPT code 99091 are needed. CPT code 99091 provides for the:

collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time.

CPT code 99091 was created in 2002 to describe the typical patient, practitioner interaction at that time. As remote monitoring technology was still nascent at that time, the code was intended to describe a scenario in which the patient purchased a home monitoring device and submitted the results to their

⁶ McGillicuddy JW et al., Mobile Health Medication Adherence and Blood Pressure Control in Renal Transplant Recipients: A Proof-of-Concept Randomized Controlled Trial, *JMIR Res Protoc* 2013 Jul-Dec 2(2): e32

⁷ Pare, G, Clinical Effects of Home Telemonitoring in the Context of Diabetes, Asthma, Heart Failure, and Hypertension: A Systematic Review, *J Med Internet Res.* 2010 Apr-Jun 12(2): e21



physician via email. Therefore, it only includes the professional component of RPM services and does not include the technical components for modern RPM service delivery.

In light of the foregoing, the DMPAG submitted an application for three new RPM codes to the CPT Editorial Panel last fall. The application sought two new codes that described the technical components of delivering RPM services and one code to describe the professional component. All three codes were adopted by the CPT Editorial Panel and are currently being considered for coverage under the 2019 Medicare Physician Fee Schedule (PFS) proposed rule. In brief, the technical components that a home health agency should provide include:

- CPT code 990X0 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment).
- CPT code 990X1 (Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days).

The new professional component is described by CPT code 994X9 (Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month). It is not expected that this would be included as an allowable cost in the home health cost report, as it is similar to CPT code 99091.

To ensure appropriate use of the codes and to enhance program integrity, the CPT Editorial Panel has provided instructions in the form of parentheticals that identify restrictions regarding reporting for 990X0, 990X1 including:

- Do not report 990X0 more than once per episode of care (see parenthetical following 990X0).
- Do not report 990X0 for monitoring of less than 16 days (see parenthetical following 990X0).
- Do not report 990X1 for monitoring of less than 16 days (see parenthetical following 990X1).

- Do not report 990X0 and 990X1 when these services are included in other CPT codes for the duration of time of the physiologic monitoring service (eg, 95250 for continuous glucose requires a minimum of 72 hours of monitoring (found in guideline language for the code subsection)).
- Do not report 990X0, 990X1 in conjunction with codes for more specific physiologic parameters (eg, 93296, 94760) (see parenthetical following 990X1).

Also, the CPT Editorial Panel has provided guidelines regarding use of these codes:

- Codes 990X0 and 990X1 are used to report remote physiologic monitoring services (eg, weight, blood pressure, pulse oximetry) during a 30-day period (see guideline language for subsection).
- To report 990X0 and 990X1, the device used must be a medical device as defined by the Food and Drug Administration, and the service must be ordered by a physician or other qualified health care professional.

To report CPT codes 990X0 and 990X1, the device used must be a medical device as defined by the U.S. Food and Drug Administration, and the service must be ordered by a physician or other qualified health care professional.

In contrast to CPT codes 990X0 and 990X1, the proposed HCPCS Level II RPM code does not have any timing parameters as to how many times it could be claimed on the cost report, does not have any limitations as to the type of device to promote patient safety, and does not account for any interaction with other codes to prevent unnecessary double billing across payment systems. While the AMA fully supports CMS efforts to promote virtual health care services, we do note that historically home health care has a high improper payment rate and is a program area that the Office of Inspector General has identified as being susceptible to fraud. Thus, ensuring proper program safeguards into the coding structure is a key to preventing fraud, waste, and abuse.

The second reason that the AMA urges CMS to utilize the new CPT codes that describe the technical components of RPM services is consistency and uniformity across the Medicare program. Different codes between home health agencies and those billing on the Medicare PFS, even though the technical components should be the same, creates a perception that they are different. This could lead to overlapping billing in the Medicare program. Therefore, not only should there be coding consistency, but there should be a clear agreement between home health agencies and providers who are billing, as to who is responsible for the technical component and associated payment capture (either as an allowable cost as part of the home health prospective payment system rate or as part of the Medicare PFS). Moreover, we recommend that CPT codes can only be billed by the home health agency or the provider. The same codes cannot be billed by both parties simultaneously.

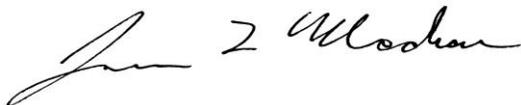
In summary, we appreciate the efforts of CMS to expand patient access and improve health outcomes utilizing clinically validated technologies.

Regulatory Burden Reduction

We applaud the ongoing initiative to identify Medicare regulations that are unnecessary, obsolete, or excessively burdensome on health care providers and suppliers. We support CMS' proposal to no longer require a home health recertification to include an estimate of how much longer skilled services will be required. Including this information as part of the recertification statement is unnecessary and duplicative of the Home Health Conditions of Participation requirements. The AMA appreciates CMS' efforts to reduce physician burden, and looks forward to working with you to identify additional areas where regulations result in the duplication of work or where physicians are being denied payment due to technical discrepancies.

Thank you for considering our views. Please contact Margaret Garikes, AMA Vice President for Federal Affairs, at margaret.garikes@ama-assn.org or by calling 202-789-7409 should you have any additional questions.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large initial "J" and "M".

James L. Madara, MD