

THE REMOTE PATIENT MONITORING INITIATIVE

901 King Street, Suite 101, Alexandria, Virginia 22314

June 6, 2011

Hand Delivered

Donald M. Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

RE: CMS-1345-P; Comments to Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule

Dear Dr. Berwick:

Thank you for the opportunity to submit comments regarding the Centers for Medicare & Medicaid Services' ("CMS") proposed rule to establish Accountable Care Organizations ("ACOs").¹ **The Remote Patient Monitoring Initiative ("RPM Initiative")** supports the establishment of ACOs. We believe Remote Patient Monitoring can help mitigate the financial risk faced by entities seeking to form ACOs, take into account patients' varying needs in care and can help ACOs meet and exceed CMS' quality and performance metrics. To that end, our comments primarily relate to the ACO program requirement in section 1899(b)(2)(G) of the Social Security Act (the "Act"). That requirement states: "***The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.***"² We look forward to working with you to make the ACO program a success.

The RPM Initiative consists of Philips Healthcare, Robert Bosch Healthcare, Cardiocom, Inc. and Honeywell International. Our companies are collaborating to increase provider awareness and patient access to home-based remote patient monitoring ("RPM") systems. Collectively, our products provide care to approximately 50% of patients benefiting from RPM in the United States. We manufacture a range of RPM products that Medicare beneficiaries can use at home to communicate their vital signs to providers who can detect abnormalities long before they become costly acute care episodes. For example, our technologies remotely monitor weight in patients with congestive heart failure (CHF) and, by detecting slight changes, avoid exacerbations of illness that

¹ Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 19528 (Apr. 7, 2011).

² Pub. L. 111-148, § 3022, codified at 42 U.S.C. § 1395jjj(b)(2)(G).

could lead to emergency room visits, hospital admissions and readmissions. Similar examples exist for other conditions as well, such as diabetes and chronic obstructive pulmonary disease (COPD), and demonstrate how RPM can improve care for patients, manage population health and lower costs to the Medicare Program.

The use of RPM is essential to not only improving quality and lowering the cost of care for patients with chronic conditions, but also improving beneficiary quality of life by minimizing unnecessary and inconvenient provider visits for mobile beneficiaries and vastly increasing immobile beneficiaries' access to care. Because of this emerging technology's promise, CMS should use this opportunity to revise the ACO proposed rule to strongly emphasize RPM. To that end, we will focus our comments on the following:

I. The statute refers to RPM separately from telehealth, therefore, we encourage CMS to treat it separately by adopting our operating definition in its final rule.

II. CMS should mirror the language under section 1899(b)(2)(G) at the appropriate place in its rule at 42 C.F.R. § 425.5 and use the preamble of the rule to discuss ways ACOs could meet this requirement.

III. CMS should require prospective ACOs to explain how they will use telehealth, RPM or other enabling technologies to meet the statutory requirements of section 1899(b)(2)(G) of the Act without being overly prescriptive. To facilitate compliance, CMS should give examples of how telehealth, RPM and other enabling technologies can be used to:

- a) Define processes to promote evidence-based medicine and patient engagement.
- b) Report on quality and cost measures.
- c) Coordinate care.

We will address each of these requests in turn.

I. The statute refers to RPM separately from telehealth, therefore, we encourage CMS to treat it separately by adopting our operating definition in its final rule.

The statute refers to RPM separately from telehealth, therefore, we encourage CMS to treat it separately by adopting our operating definition in its final rule. Our operating definition is as follows:

Remote Patient Monitoring is a coordinated system that:

- uses a one or more home-based monitoring devices that:
 - automatically transmit vital sign data and responses to assessment questions collected on the devices wirelessly or through a telecommunications connection to a server that complies with the HIPAA privacy and security rules in Parts 160 and 164 of title 45, Code of Federal Regulations; and
 - are accessed by a patient at the direction of a health care professional; and
- includes the review and interpretation of that data by a health care professional as part of an established plan to care for that patient.

We strongly recommend CMS adopt and include our operating definition in its Final Rule, given its consensus development by RPM system manufacturers and other industry experts.

II. CMS should mirror the language under section 1899(b)(2)(G) at the appropriate place in its rule at 42 C.F.R § 425.5 and use the preamble of the rule to discuss ways ACOs could meet this requirement.

CMS should mirror the statutory language in its proposed regulation at the appropriate place in 42 C.F.R. § 425.5 as follows: “*The ACO shall define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.*”³ It is necessary to include this language in the regulation to ensure it is recognized as a statutory requirement. After this change is made, the preamble to the rule can be appropriately used to discuss how ACOs can meet this requirement.

In addition, we encourage CMS to interpret the use of telehealth, RPM and other such enabling technologies as applying to each of the antecedent clauses (promoting evidence-based medicine and patient engagement, reporting on quality and cost measures and coordinating care). Not only is this a reasonable reading of the statutory language, but as is demonstrated in our comments below, RPM plays a key role in each of these areas.

III. CMS should require prospective ACOs to explain how they will use telehealth, RPM or other enabling technologies to meet the statutory requirements of section 1899(b)(2)(G) of the Act without being overly prescriptive.

In section II.B.9 of the preamble to the proposed rule, CMS presents two extreme options regarding the implementation of section 1899(b)(2)(G) of the Act.⁴ The two options are either to copy the language directly from the statute and require documentation of an ACO’s plans to comply with that language without further guidance (Option 1), or at the other extreme, limit ACO’s innovation and experimentation by imposing strict, complex and burdensome regulatory requirements by prescribing how ACOs must meet the requirement (Option 2).

We believe there is a more beneficial option in which CMS gives ACO design models that incorporate RPM technologies priority application review and consideration. CMS should require prospective ACOs to explain how they will use telehealth, RPM or other enabling technologies to meet each of the antecedent statutory requirements.

CMS should give examples of how prospective ACOs could use these types of technologies to define processes to promote evidence-based medicine and patient engagement, report on quality and costs measures and coordinate care. This will be helpful to prospective ACOs without being too restrictive as to how they design their models. We provide some specific examples for CMS’ consideration below.

A. Define processes to promote evidence-based medicine and patient engagement.

RPM collects data regarding the patient’s management of their condition measured against the

³ Section 1899(b)(2)(G) of the Act, as added by Pub. L. 111-148, § 3022, codified at 42 U.S.C. § 1395jjj(b)(2)(G).

⁴ *ibid.*

guidelines developed by key organizations. For example, with respect to patients with chronic heart failure (CHF), RPM compares patient progress to the guidelines set by the American Heart Association and the Heart Failure Society of America. For patients with diabetes, RPM uses the American Diabetes Association's guidelines. For pulmonary conditions, such as COPD, RPM uses guidelines published by the National Heart, Lung and Blood Institute of the National Institutes of Health. The frequency and relevance of the data collected and comparing it to the clinical guidelines and outcomes supports evidence-based medicine and can be used to improve care for all Medicare beneficiaries. In addition, RPM permits clinicians to use that data to prioritize patient interventions.

Likewise, RPM can play a key role in promoting evidence-based medicine and patient engagement. For example, Medicare beneficiaries using RPM must submit their vital signs each day or their clinician will call them. The action of the beneficiary in taking these daily measurements raises their awareness of how well they are managing their condition. RPM further supports patient engagement by ensuring that patients receive education and coaching regarding management of their condition and tests that knowledge as well.

B. Report on quality and cost measures.

1. Quality Measures

Patients, payers and providers can use RPM both to improve the quality of care furnished to patients in an ACO and to improve ACO performance under numerous quality measures included as part of an ACO's requirements. Two obvious examples are the measures relating to weight measurement in Medicare beneficiaries with heart failure and blood pressure control in Medicare beneficiaries with hypertension:

- **Measure 47 – Heart Failure: Weight Measurement.** “Percentage of patient visits for patients aged 18 years and older with a diagnosis of heart failure with weight measurement recorded.”

While this process measure specifies patient visits, the technologies described above allow weight to be taken in the home on a daily basis. This provides the opportunity for continual weight monitoring and early intervention, preventing potential hospital admission due to heart failure.

- **Measure 58 – Hypertension: Blood Pressure Control.** “Percentage of patients with last BP<140/90 mmHg.”

This outcome measure does not specify that the patient's blood pressure needs to be taken during an office visit. The technologies described above are able to record blood pressure and transmit to a provider, having the potential to decrease the frequency of office visits (and their associated costs to beneficiaries and Medicare) as well as monitor blood pressure on a daily basis, allowing early intervention and preventing potential hospital admissions.

2. Cost Measures

Numerous studies show that RPM and telehealth technologies improve quality while lowering the cost of care, especially for patients with chronic conditions, including:

- 25% reduction in bed days of care within multi-chronic conditions.⁵
- 19% reduction in hospitalizations within multi-chronic conditions.⁶
- 50% reduction in re-hospitalizations for CHF.⁷
- A 7% reduction (\$48 billion) in domestic costs associated with chronic conditions.⁸

In addition, a recent evaluation of The Health Buddy Program, a telehealth-enabled care management program that is part of the CMS Care Management for High Cost Beneficiaries Demonstration, conveys the following key findings:

- All-cause hospitalizations declined within the intervention group while the rate of all-cause hospitalizations increased within the comparison group.
- There was a lower rate of mortality among intervention beneficiaries that used the RPM device.
- Beneficiaries using the RPM device exhibited a slower rate of cost growth.

The study specifically targeted beneficiaries with diabetes, heart failure, COPD and hypertension/coronary artery disease. The evaluation report concludes there is an “incremented increase in survival benefit and lower cost increases among intervention beneficiaries who used the Health Buddy device.”⁹ We believe this growing body of evidence supports our call for clearer RPM language and specific requirements in the guidelines.

C. Care Coordination

CMS should very clearly emphasize the use of telehealth and RPM technologies as an extremely important aspect of the care coordination process.

In recent years, the increasing number of patients with manageable chronic conditions has created a burden for physician practices and a fragmented delivery system. Further, mis-aligned incentives have made it difficult to improve outcomes and manage costs. The Affordable Care Act (ACA) addresses this challenge by emphasizing alignment of incentives through delivery and payment system reform. The Act also recognizes the critical role of care coordination and care managers.

⁵ Darkins et al. (2008): Care Coordination/ Home Telehealth – The Systematic Implementation of Health Informatics, Home Telehealth, and Disease Management to Support the Care of Veterans with Chronic Conditions. *Telemedicine & e-Health*, 14(10), 1118-26.

⁶ *ibid.*

⁷ Weintraub AJ et al. (2010): A Multicenter Randomized Controlled Evaluation of Automated Home Monitoring and Telephonic Disease Management in Patients Recently Hospitalized for Congestive Heart Failure: The SPAN-CHF II Trial. *Journal of Cardiac Failure*, 16 (4), p 285-292.

⁸ Consortium savings estimate, based on Medical Association total condition cost estimates.

⁹ McCall, N., Cromwell, J., Smith, K., & Urato, C. (2011). *Evaluation of Medicare Care Management for High Cost Beneficiaries (CMHCB) Demonstration: The Health Buddy Consortium (HBC)* (RIT Project Number 0207964.025.000.001). http://www.cms.gov/Reports/Downloads/McCall_Eval_of_CMHCB_Demo_April_2011.pdf.

RPM assists the care coordination process by promoting contact with the patient in advance of an acute care episode. Advanced detection enables care managers to make a clinical assessment, intervene if warranted and provide physicians with granular detail about symptoms as needed, thereby creating rapid and targeted response to signs of complications. For instance, each morning clinicians using remote patient monitoring in the home health industry receive vital and symptom information from tens of thousands of home-based patients. These clinicians use this information to immediately re-route hundreds of travelling nurses to the homes of patients that appear most at risk of a hospital readmission. This tight coordination of these essential care resources is one of the main reasons RPM has experienced such a high success rate to date.

Remote Patient Monitoring significantly reduces the risk of death, hospitalization for any cause, and the hospitalization for heart failure compared with usual care. We believe this is because patients utilizing RPM become more knowledgeable about their conditions, learn to recognize signs of complications and are comfortable engaging their care manager. All of these actions potentially avert unnecessary office visits and reduce system congestion caused by patients with ambiguous vital signs and preventable complications.

Conclusion

For the reasons stated above, we respectfully advise that:

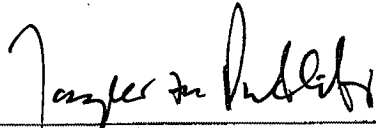
1. CMS should honor statutory intent and treat remote patient monitoring separately from telehealth by adopting our recommended definition of remote patient monitoring in the final rule.
2. CMS should mirror the statutory language of section 1899(b)(2)(G) of the Act in its proposed regulation at the appropriate place in 42 C.F.R. § 425.5 and then elaborate on how ACOs are expected to meet this requirement in the preamble to the rule.
3. In section II.B.9 of the preamble to the proposed rule, we recommend that CMS reject both options it presents and adopt an alternative approach that requires prospective ACOs to explain how they will use telehealth, RPM or other enabling technologies to meet each of the statutory requirements included in section 1899(b)(2)(G) without being overly prescriptive. CMS could accomplish this by giving illustrative examples of how ACOs could use RPM and the other technologies mentioned in that section.

Again, thank you for the opportunity to comment on the Medicare Shared Savings Program: ACOs Proposed Rule. We appreciate your consideration of our comments.

If you have any questions, need more information or would like to meet with the Remote Patient Monitoring Task Force, please contact Daniel Cosentino at 888.243.8881 or dcosentino@cardiocom.com.

Sincerely,

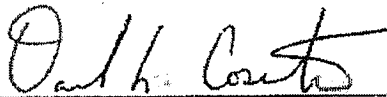
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