Remote Patient Monitoring Opportunities and Risks for Technology Vendors and Providers

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In recent years, the Centers for Medicare and Medicaid Services (CMS) has expanded coverage for remote patient monitoring (RPM) services under Medicare.

RPM services include establishing, implementing, revising, and monitoring a specific patient treatment plan related to one or more chronic conditions. RPM may be used to promote proactive patient self-care, monitor patients' key measures, and allow providers and patients easy access to information about patient health issues.

In the 2020 Medicare Physician Fee Schedule, CMS finalized changes related to RPM services that present new opportunities.[1] CMS's changes provide for both new reimbursement and greater flexibility in the way RPM services can be furnished. As a result, technology vendors, physician practices and potentially other entities can now explore new ways to collaborate, such as through models in which the vendors provide clinical staff to perform RPM services through their technology under the billing practitioner's general supervision.

The new payment and reimbursement for RPM presents both opportunities and compliance challenges. Below we review the changes and potential new service model opportunities, along with key compliance considerations including those relating to clinician licensure, billing compliance and open issues that remain to be addressed regarding RPM services.

RPM Service Opportunities

RPM services are covered and paid for by Medicare when furnished directly by or "incident to" the services of a physician or a Qualified Health Professional (QHP) (collectively referred to in this article as "practitioner" or "billing practitioner").[2] Coverage for RPM has been available since 2018,[3] but starting January 1, 2020, CMS will:

- Recognize a new code (99458) to allow physicians and QHPs to be paid for additional time (beyond the first 20 minutes under code 99457) spent managing care and interpreting physiologic data; and
- Allow RPM professional codes (99458 and 99457) to be furnished under the general supervision of the practitioner, as opposed to *direct* supervision as required for most incident to services.[4]

These changes, in combination, will permit technology vendors and other third parties who have not historically been involved in the delivery of direct patient care to engage in RPM arrangements that support physicians and other care providers.

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One potential model would involve vendor-owned/operated companies hiring and providing the services of clinical personnel (e.g., nurses and others) to support physicians and other QHPs in multiple jurisdictions. The remote nature of RPM provides greater flexibility to support RPM services in multiple organizations and geographic settings.

The opportunities for new business models and service delivery strategies are obvious, but such new structures are also associated with compliance risk, as discussed below.

Key Business and Compliance Considerations

Getting Paid

Many states place restrictions on the ability of unlicensed entities and individuals to own and operate companies that engage in the practice of medicine and other health care professions, including nursing.

Likewise, Medicare and other payors of health care services will only make payment to individuals or entities that are themselves qualified under applicable state law to engage in the particular activity and that are enrolled to receive payment from the payor. Yet that may not always be the case for technology vendors and others who undertake to directly provide and receive payment for RPM services. These non-traditional providers will need to either address these enrollment and payment issues (e.g., in states without corporate practice of medicine or similar restrictions) or, more likely, use business models that involve partnering with or providing services to practitioners who already have those qualifications in place.

State Law Licensure, Scope of Practice, Delegation and Telemedicine Requirements

Under both the Medicare rules as well as the CPT code definitions for 99457 and 99458, RPM services may be furnished by physicians, other qualified health care professional and "clinical staff" (referred to as "auxiliary personnel" under the Medicare rules). While RPM are likely within the authorized scope of practice for physicians and other qualified health care professionals (such as nurse practitioners and physician assistants), that is less certain in the case of other "clinical staff" such as nurses, medical assistants or other unlicensed personnel furnishing RPM services in support of another billing practitioner, depending on what those RPM services entail.

CPT defines a clinical staff member as "a person who works under the supervision of a physician or other qualified health care professional and who is *allowed* by law, regulation and facility policy to perform or assist in the performance of a specified professional service; but who does not individually report that professional service."

Medicare similarly defines "auxiliary personnel" as any individual acting under the supervision of a physician or QHP who is an employee, leased employee, or independent contractor and who *meets all state requirements* to furnish the service.[5]

These definitions require the clinical staff engaging in RPM services to comply with state law applicable to the arrangement and their services. This means that for a vendor to hire or retain nurses and other licensed professional clinical staff to provide some aspects of clinical decision-making and remote care for RPM, the vendor must first ensure that the laws in the particular state(s) in which the services are being furnished (i.e., where the patient is located) allow it.

First, the above-referenced "corporate practice" restrictions are designed to prevent undue influence from unlicensed parties on the professional practice. Therefore, if a vendor hires nurses to provide RPM services under contract to medical practices, the vendor must ensure that the state's law does not prohibit the vendor from hiring and engaging in the practice of professional nursing.

Second, the clinical staff must be qualified to perform the RPM services under applicable state law. This requires a review of the proper licensure and any "scope of practice" limitations in the state(s) in which the clinical support staff are furnishing clinical care. And where the clinical personnel engaged in RPM service delivery are not separately licensed in a discipline with its own scope of practice, state law requirements related to the delegation of services from separately licensed professionals (i.e., physicians, NPs, PAs) to unlicensed personnel must also be considered in relation to the activities actually being undertaken by the clinical staff supporting RPM.

Additionally, the technological capabilities of RPM create opportunities for nurses and other qualified clinicians to support patient care across long distances and in multiple states. Because applicable laws governing clinician licensure and scope of practice depend on where the patient is located, it is possible that a single nurse could be engaged in the practice of nursing in multiple states and, therefore, obligated to comply with the laws in each of those states in connection with the RPM services furnished.

RPM services do not meet the definition of telehealth under Medicare rules and, therefore, are not equally restricted with regard to patient origination and type of patient interaction; however, vendors and billing practitioners must be mindful of state telemedicine and telehealth requirements. Particularly given that CPT codes 99457 and 99458 are vague with regard to the meaning of "interactive communication," billing practitioners, vendors, and the clinical staff should ensure that the services they provide are compliant with any state law requirements.

Billing and Supervision Requirements

Regardless of the extent of the RPM services that a vendor and its clinical staff furnish—ranging from monitoring physiologic data to communicating with patients and/or updating treatment plans—the billing practitioner (i.e., physician, nurse practitioner or physician assistant) must ensure that the Medicare incident to billing requirements are met.

Generally, services billed as "incident to" must be an integral, though incidental, part of the billing practitioner's service in the course of the patient's diagnosis or treatment.[6] This means the practitioner submitting the bill must furnish an initial service (e.g., an E/M visit) to which the subsequent RPM services are integral and incidental, establishing the patient relationship prior to furnishing RPM.

Starting January 1, 2020, RPM services reported with CPT codes 99457 and 99458 may be billed incident to under "general supervision" rather than the "direct supervision" standard otherwise required. General supervision means the service is furnished under the billing practitioner's overall direction and control, but the billing practitioner is not required to be physically present or located within the same office building.[7]

In practical terms, by permitting RPM services to be furnished under general supervision, physician practices and other billing providers can potentially outsource aspects of the RPM services to off-site or remote vendors on a full or part-time basis. And this change will permit vendors to develop and deploy, subject to the state law issues discussed above, business models involving groups of vendor-employed clinicians supporting billing providers remotely via technology.

For the billing practitioners to avoid potential billing compliance issues, the RPM vendor services should be structured in a way that allows the billing practitioners the "control," on-going participation in and management of the course of each patient's treatment. For example, this could mean that the vendor and clinical staff would collect data and alert the practitioner of any significant findings per the practitioner's treatment protocol. The practitioner would then use this data to interact with the patient and adjust the treatment plan.

We caution that a purely passive model (in which the billing practitioner has little to no involvement in the service design or implementation) will likely increase compliance risk that, on audit, CMS may view such billing as not in fact "incident to" the practitioner's service and, therefore, not covered--potentially implicating overpayment allegations.

For the same reasons, these requirements have implications for technology vendors developing service bureau-type business models to provide RPM services. Such vendors should address:

- How and by what type of clinical staff their clinical services will be deployed through their technology,
- How their clinical services will assist the practitioners to furnish RPM services, and
- The means by which the vendor's company will interact with and permit the billing practitioners to control and engage with the services being provided (e.g., through protocol development, live communication between the RPM vendor clinical staff and the billing provider and other means).

Other Compliance Considerations and Uncertainties

RPM service models will also drive new data privacy and security considerations under the Health Insurance Portability and Accountability Act (HIPAA) as well as state law. The scope of the issues will evolve with RPM and the technology used to provide it, but in general, providers and vendors must understand the vendor's role—whether acting as a provider and, therefore, a covered entity under HIPAA, or whether acting as a business associate that performs functions or activities on behalf of the practitioners.

If the vendor is functioning as a business associate, the vendor-practitioner service agreement and the business associate agreement should outline the practitioner's and the vendor's RPM related data ownership, including related to the original, de-identified, aggregated, and derivative data. And since the RPM services can and frequently will be provided in multiple jurisdictions (i.e., where the patient being monitored is located) the nuances of those state laws governing clinical data, privacy and security need to be considered and complied within the operating model.

There are also a number of open questions related to RPM and how the benefit may be expanded, limited, or further regulated in the future. The potential for changes will require providers and vendors to monitor the annual rulemaking and build their contractual arrangements to be flexible in anticipation of those changes.

For example, in the CY 2020 Physician Fee Schedule Final Rule, CMS described the an RPM service as follows:

> **CPT Code 99457:** (base code, treatment management services – monthly payment) Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month *requiring interactive communication with the patient/caregiver during the month*; initial 20 minutes;

Certain of the terms in that CPT code description are undefined and CMS has indicated that it will provide clarification in future rulemaking, including:

- Who can furnish and bill for RPM services (although arguably these are defined by state law and the Medicare regulations);
- Documentation requirements for RPM services; and
- Various key definitions and terms including what constitutes a patient's physiologic parameters, digitally transmitted data (as opposed to patient-reported data), what qualifies as a "medical device" that can be used in RPM services, and, as noted above, what constitutes "interactive communication."

While these issues will likely get sorted out over time, and new issues will arise, all parties involved in vendor-driven business and service models involving RPM will need to pay close attention to the regulatory landscape and be prepared to refine arrangements in response.

Endnotes/Citations

[1] Final Physician Fee Schedule Rule CY 2020, 84 Fed Reg. 62568, 62697-62698 (Nov. 1, 2020).

[2] Under the AMA definition, a QHP as an "individual who is qualified by education, training, licensure/regulation (when applicable), and facility privileging (when applicable) who performs a professional service within his/her scope of practice and independently reports that professional service." American Medical Association, 2019 CPT Professional, page 5. In Medicare terms, a QHP is a practitioner who is authorized to receive payment for services incident to his or her services (e.g., nurse practitioners, physician assistants, certified nurse midwife, or clinical nurse specialist). 42 C.F.R. § 410.26(a)(7).

[3] CMS originally covered RPM through CPT code 99091, which was a limited treatment management code. In 2019, CMS expanded the suite of codes and replaced 99091 with 99453, 99454, and 99457).

[4] Final Physician Fee Schedule Rule CY 2020, 84 Fed Reg. 62568, 62697-62698 (Nov. 1, 2020).

[5] 42 C.F.R. § 410.26(a)(1).

[6] 42 C.F.R. §410.26(b).

[7] 42 C.F.R. § 410.26(a)(3).

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