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DMEPOS

Hot Button Legal Issues Facing DME Suppliers

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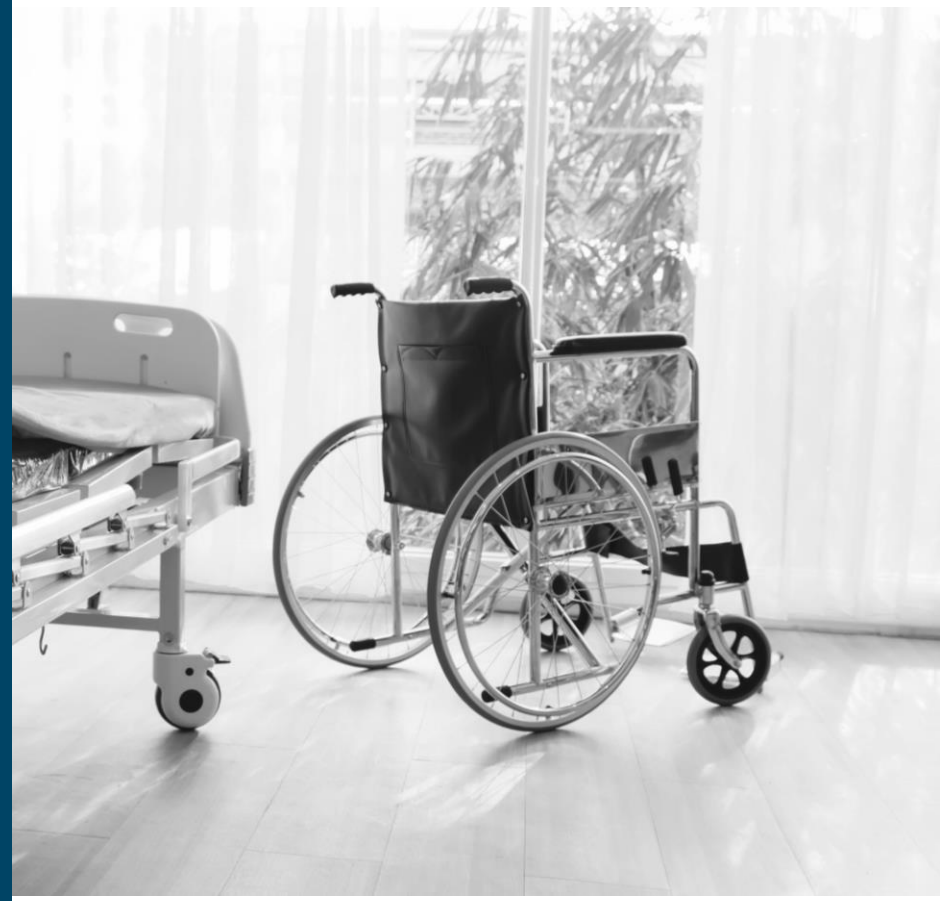

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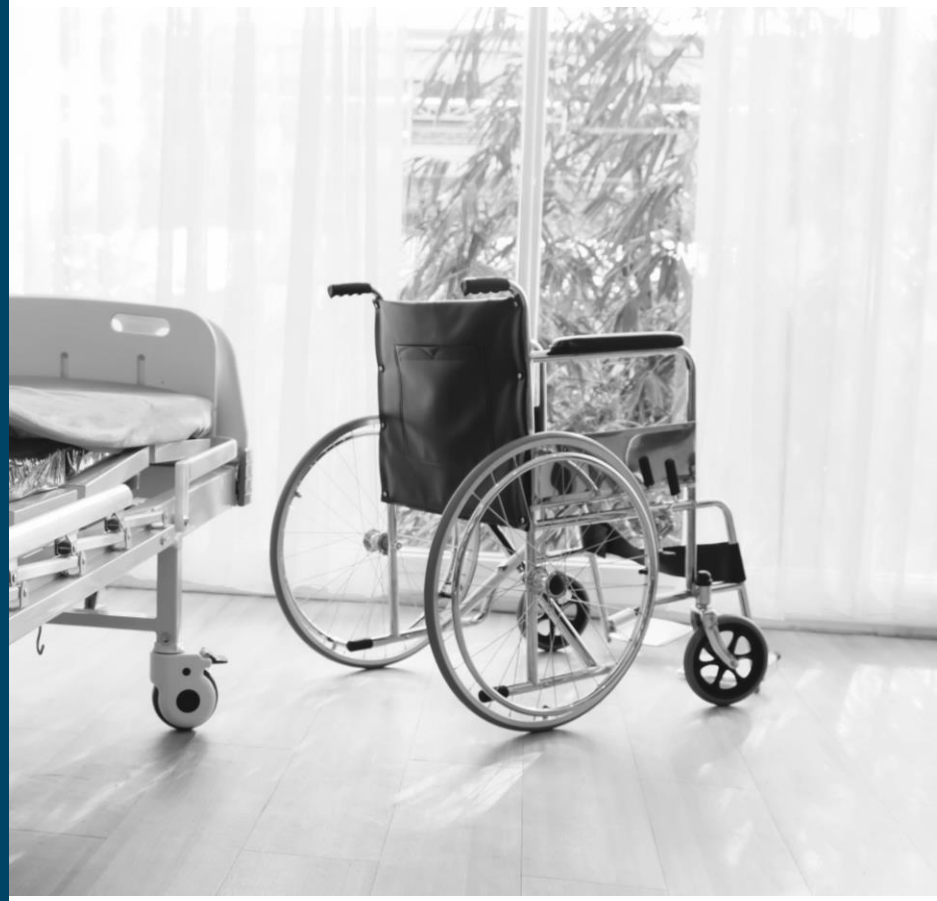
Introduction



Products Added to Face-to-Face Encounter and WOPD List

- On January 13, 2022, CMS published the HCPCS codes that will be added to the list of products that require a face-to-face encounter and written order prior to delivery (WOPD) as well as the HCPCS codes added to the list of products that require prior authorization.
- The following HCPCS codes will require a face-to-face encounter and WOPD effective April 13:
  - E0748, L0648, L0650, L1832, L1833, L1851, L3960
- For items on the Face-to-Face Encounter and WOPD List, the completed Standard Written Order (SWO) must be communicated to the supplier prior to delivery.

Products Added to Face-to-Face Encounter and WOPD List

- CMS also reiterated that if the face-to-face encounter is a telehealth encounter, the requirements of 42 CFR 410.78 and 414.65 must be met for DMEPOS coverage purposes.
- These are the sections that require interactive audio and video communication and that the patient be located at a qualified "originating site."
- Some of these requirements have been waived for the duration of the Covid Public Health Emergency (PHE) period.

Products Added to the Prior Authorization List

- The HCPCS codes being added to the list of products requiring prior authorization are:
  - K0800, K0801, K0802, K0806, K0807, K0808, L0648, L0650, L1832, L1833, L1851
- The prior authorization requirement for the power mobility device HCPCS codes is effective April 13, 2022.

Products Added to the Prior Authorization List

- The implementation of the prior authorization requirement for the orthotic products is being conducted in three phases.
  - Phase 1 effective April 13, 2022
    - New York, Illinois, Florida, and California
  - Phase 2 effective July 12, 2022
    - Phase 1 states and Maryland, Pennsylvania, New Jersey, Michigan, Ohio, Kentucky, Texas, North Carolina, Georgia, Missouri, Arizona, and Washington
  - Phase 3 effective October 10, 2022
    - Nationwide

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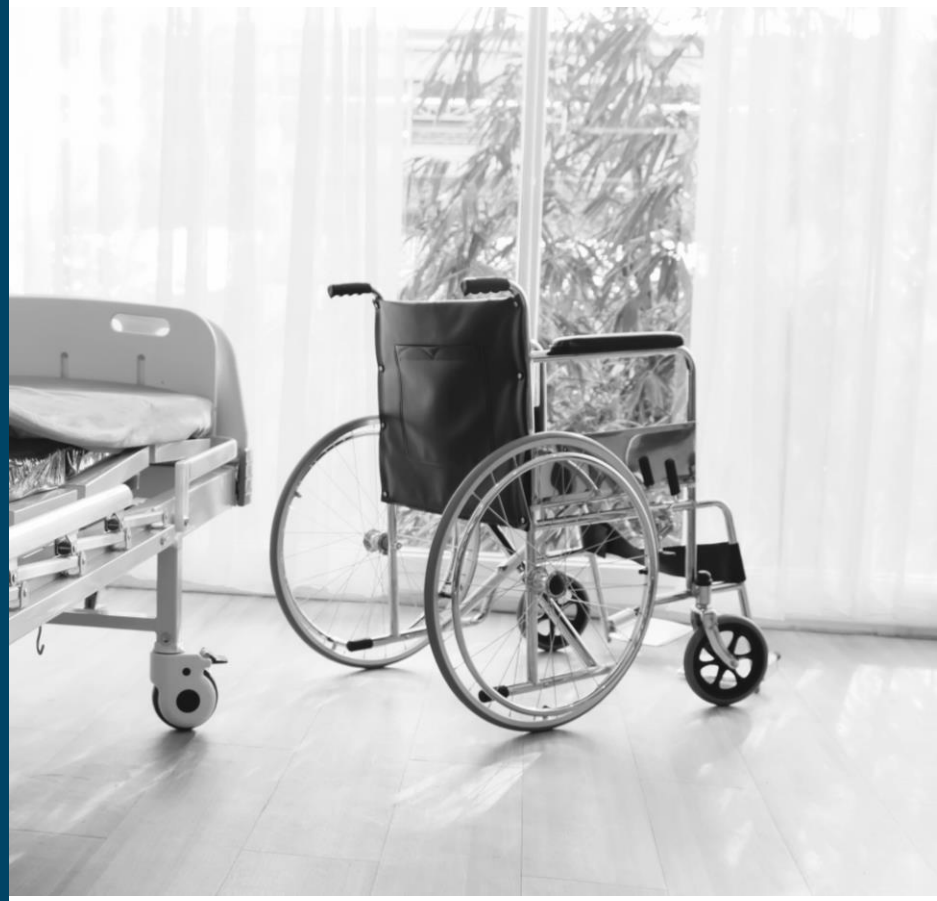
DME Supplier and Home Sleep Test



DME Supplier and Home Sleep Test

- An increasing number of patients are being diagnosed with obstructive sleep apnea ("OSA"). As a result, we are seeing an expansion of sleep labs, but such expansion is focused on home sleep tests ("HSTs"), as opposed to overnight attended polysomnographies.
- The push for HSTs is driven by economics. Simply speaking, HSTs are less expensive to administer, and are less intrusive, than attended overnight tests.
- Sleep labs are closely tied to DME suppliers in the sense that if a patient tests positive for OSA, then he will need sleep therapy … normally in the form of a CPAP.
- For purposes of this presentation, we will break down OSA patients into two categories: Medicare patients and commercial insurance patients. Medicare rules pertaining to HSTs and DME suppliers are stricter than rules published by commercial insurers.

Medicare CPAP Payment Prohibition

- As noted above, the increased demand for CPAPs and disposables creates opportunities for DME suppliers.
- However, a word of caution must be noted: if the patient is covered by Medicare, the DME supplier can have no involvement with an HST.

Medicare CPAP Payment Prohibition

- Let's make a distinction.
  - Overnight Oxygen Qualification Test
    - A DME supplier can have some involvement with an overnight oxygen qualification test provided to a Medicare patient. The supplier can (i) deliver the oximeter to the Medicare beneficiary's home, (ii) pick up the oximeter the next morning, and (iii) transmit the raw data to the IDTF. If the physician orders oxygen for the beneficiary, and if the beneficiary chooses to obtain the concentrator from the DME supplier that served as courier for the oximeter, then the DME supplier can provide the concentrator to the beneficiary.

Medicare CPAP Payment Prohibition

- HST
  - Logic would suggest that a DME supplier can have the same involvement with an HST and be able to provide the CPAP to the Medicare beneficiary. This is not the case. Assume that ABC Medical Equipment, Inc. owns HST devices. The beneficiary's physician orders an HST for the beneficiary. At the physician's request, ABC delivers the HST device to the beneficiary, assists the beneficiary with set-up and use of the HST device, retrieves the HST from the beneficiary the next morning, and transmits the test results to the physician. If the physician orders a CPAP for the beneficiary, and if the beneficiary elects to obtain the CPAP from ABC, then if ABC provides the CPAP it violates the Medicare CPAP payment prohibition.

Medicare CPAP Payment Prohibition

- No Medicare payment will be made to the supplier of a CPAP device if that supplier, or its affiliate, is directly or indirectly the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.

Medicare CPAP Payment Prohibition

- It is important to understand how Medicare defines an “affiliate.”
- The definition of an “affiliate” for purposes of the prohibition is “a person or organization that is related to another person or organization through a compensation arrangement or ownership.” The term “compensation arrangement” is not defined in the section of the CMS regulations that the prohibition appears, but the same term is used in, and defined by, the Stark statute as “any arrangement involving any remuneration . . . .”

Medicare CPAP Payment Prohibition

- Medicare will not pay ABC for the CPAP if ABC is the “provider of the sleep test.”
- That term is defined as “the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test.”

Medicare CPAP Payment Prohibition

- When promulgating this definition, CMS provided some clarity in the Final Rule when it stated the following:
  - We have defined a provider of sleep test as an individual or entity that directly or indirectly administers and/or interprets the test and/or furnishes the sleep test device. By indirect we mean that one or more intermediary actors are used to accomplish the sleep test to its end. For example, if a DME supplier contracted with a sleep test provider to furnish HST, that supplier would indirectly provide the HST. Directly providing the test means there are no intermediary actors—no intervening persons or entities between them.

Medicare CPAP Payment Prohibition

- In our example, because ABC furnishes the HST device to the beneficiary, there is a risk that ABC will be considered as the “provider” of the test. Because the physician will actually be the individual to submit claims for the sleep test, it can be argued that the physician (not ABC) is the direct provider of the HST. However, there is a risk that ABC will be considered an “indirect provider” of the HST because ABC is the entity that:
  - Delivers the HST device,
  - Assists the beneficiary through the set-up and education process,
  - Retrieves the HST device from the beneficiary, and
  - Transmits the data to the physician.

Medicare CPAP Payment Prohibition

- The safest course of action is for the DME supplier to have no involvement with the HST administered to a Medicare beneficiary.
- Finally, let me make several additional points:
  - This payment prohibition applies to Medicare fee-for-service (“FFS”) patients. As to whether or not there is a similar prohibition with commercial insurance patients (including Medicare Advantage patients), the supplier will need to examine the insurance contracts and the insurance company’s payment/coverage guidelines.

Medicare CPAP Payment Prohibition

- Finally, let me make several additional points (cont'd):
  - If a supplier determines that it has violated the payment prohibition, then the supplier needs to refund the money it has been paid for the CPAPs and the disposables.
  - Where the payment prohibition can come into play for the DME supplier is when it is about to sell. In conducting due diligence, if the buyer determines that the payment prohibition has been violated, then it is likely that:
    - The purchase price will be lowered or
    - The buyer will walk away.

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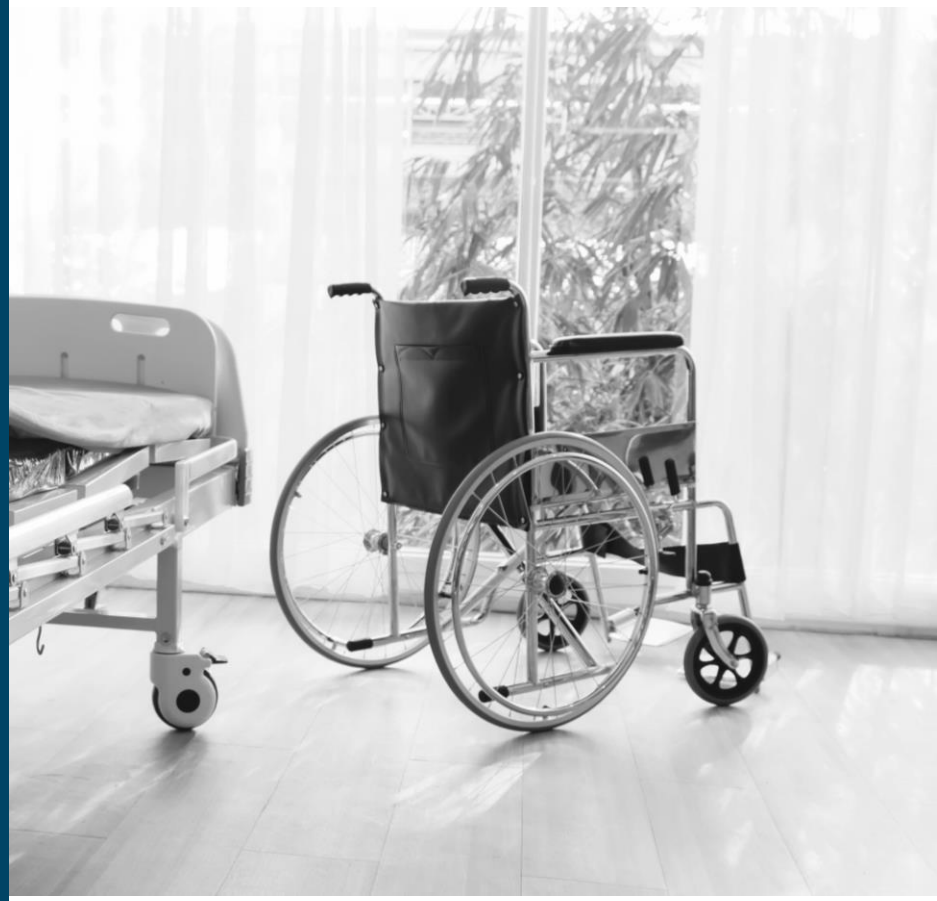
Telehealth



Introduction

- In the years leading up to the pandemic, health care delivery had been shifting towards telehealth. This made sense because many health care encounters did not need to be face-to-face.
- A number of ailments can be diagnosed via a live video conference with the physician. A number of treatments can be ordered via a live video conference with the physician. A patient's vital signs can be monitored with remote technology.

Introduction

- A DME supplier can utilize technology to:
  - Assist the patient in setting up his equipment and
  - Educate the patient on how to use the equipment.
- In short, there are many scenarios in which a patient should not have to leave the confines of his home to receive health care.
- Pre-pandemic, the shift towards telehealth had been led by commercial insurers, not by Medicare.
- Commercial insurers were more open to telehealth than the Medicare program.
- Insurers recognized the cost saving benefits of telehealth; Medicare was slow to follow the private sector's lead.

Introduction

- But then COVID changed everything.
- Beginning in March 2020, the health care delivery system went into triage mode.
- The focus was to keep as many patients as possible out of the hospitals… so as to free up hospital beds for the sickest.
- The focus was to diagnose and treat patients as rapidly as possible. Many physicians had to close their offices and/or limit their availability for face-to-face encounters with patients.
- DME suppliers had to figure out how to take care of their patients without having face-to-face contact.

Introduction

- Out of necessity, technology had to be relied on … and third party payors (“TPPs”), including Medicare, had to accept the reality of relying on telehealth.
- And so this is the point where the law had to scramble to keep up with the unfolding events on the ground.
- The pandemic is a “game changer.”
- What this means is that COVID greatly accelerated the shift to telehealth.
- COVID accomplished in months what would normally have taken years to accomplish if the pandemic never occurred.

Medicare, DME, and Telehealth

- Pre-pandemic DME suppliers were limited in their ability to rely on physicians' orders resulting from telehealth encounters between Medicare beneficiaries and physicians.
- Pre-pandemic, in order for Medicare to recognize a physician's order for DME, resulting from a telehealth encounter, several limiting elements had to be met.
- The beneficiary had to reside in a rural area. The beneficiary had to leave his residence and drive to an "originating site" (e.g., critical access hospital).

Medicare, DME, and Telehealth

- Once inside the originating site, the patient was required to have both a visual and audio telehealth encounter with the physician.
- These limitations were laid bare by Operation Brace Yourself in which DME suppliers, lead generation companies, telehealth companies and telehealth physicians were targets of kickback investigations because payments to the physicians (who prescribed braces) emanated from the DME suppliers that sold the braces … and billed Medicare.

Medicare, DME, and Telehealth

- In addition to the criminal cases, a number of DME suppliers (i) were subjected to recoupment actions and/or (ii) had their Medicare payments suspended.
- The recoupments/suspensions were based on the fact that the three elements set out in the preceding paragraph were not met.
- That is:
  - Many Medicare beneficiaries resided in non-rural areas,
  - Most of the beneficiaries never left the confines of their homes, and
  - Most of the beneficiaries only had telephone conversations with the prescribing physicians.

Medicare, DME, and Telehealth

- There is no question but that the back brace/lead generation/telehealth arrangements “gamed the system” and had to be stopped.
- And yet, when the pandemic hit Medicare determined that the telehealth restrictions needed to be relaxed during the pandemic.
- It was obvious that DME suppliers had an important role in keeping patients out of the hospital.
- If DME suppliers could take care of patients in their homes with a combination of equipment and services, then undue restrictions should not be placed on the suppliers.

Medicare Policy Changes

- Policy Changes
  - Since early March 2020, CMS has issued a number of waivers, regulations and rules pertaining to telehealth. In doing so, CMS:
    - Expanded the health care workforce by removing barriers to providing care;
    - Removed regulatory barriers with the goal of ensuring that hospitals can handle a surge of COVID patients; and
    - Removed regulatory barriers with the goal of ensuring that patients have access to care while remaining at home.

Medicare Policy Changes

- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 6, 2020)
  - Pursuant to this Act, Congress authorized HHS to waive certain Medicare telehealth requirements. The Act expands coverage to:
    - Patients outside of rural areas;
    - Patients in their homes; and
    - New (not just established) patients.

Medicare Policy Changes

- Coronavirus Preparedness and Response Supplemental Appropriations Act (March 27, 2020)
  - This Act allows HHS to waive statutory coverage requirements for telehealth. The Act further increased funding for e.g., remote care technologies. The Act is effective through the end of the Public Health Emergency ("PHE").
- New CMS Rules
  - CMS issued rules (CMS-1744-IFC, CMS-5531-IFC) and FAQs addressing telehealth expansion during the PHE. Medicare now pays for telehealth services at the same rate as in-office visits for all diagnoses, not just services related to COVID. Physicians can reduce or waive Medicare beneficiary cost-sharing for telehealth visits, virtual visits, e-visits, and remote monitoring services.

Medicare Policy Changes

- Medicare Telehealth Changes
  - Patients can receive telehealth and other technology-based services wherever the patients are located. Telehealth services can be provided to new or established patients. Certain evaluation and management (“E & M”) services, behavioral health visits, and educational services can be provided via audio only. Other services must be furnished with audio and video technology, but IT and location requirements have been relaxed.

Medicare Policy Changes

- Medicare Telehealth Changes
  - CMS has expanded the types of practitioners who may provide telehealth services. Telehealth can now be billed by all provider types who are eligible to bill Medicare for their professional services. CMS can add new CPT codes to the list of services that can be provided via telehealth on a sub-regulatory basis, which will result in the quicker addition of CPT codes to the list of codes that may be provided by telehealth. Clinicians can provide (i) remote evaluation of patients and (ii) virtual check-in services to both new and established patients. Medicare payment for telephone E & M codes are equivalent to payment for office and/or outpatient visits with established patients. Clinicians can provide remote patient monitoring services to both new and established patients and these services can be provided to patients with only one disease. To the extent that an NCD or LCD would require a face-to-face visit for evaluations and assessments, clinicians do not have to meet those requirements for the duration of the PHE. This, however, does not apply to power mobility devices.

Future of Telehealth

- Most experts anticipate that the expansion of telehealth is here to stay. The best analogy may be that we are experiencing 10 or more years of progress towards telehealth in a matter of months. It is unlikely that all of this progress will be reversed. President Trump signed multiple executive orders with an intent to expand telehealth and to make some of these changes permanent. HHS has demonstrated a willingness to make some of these changes permanent.

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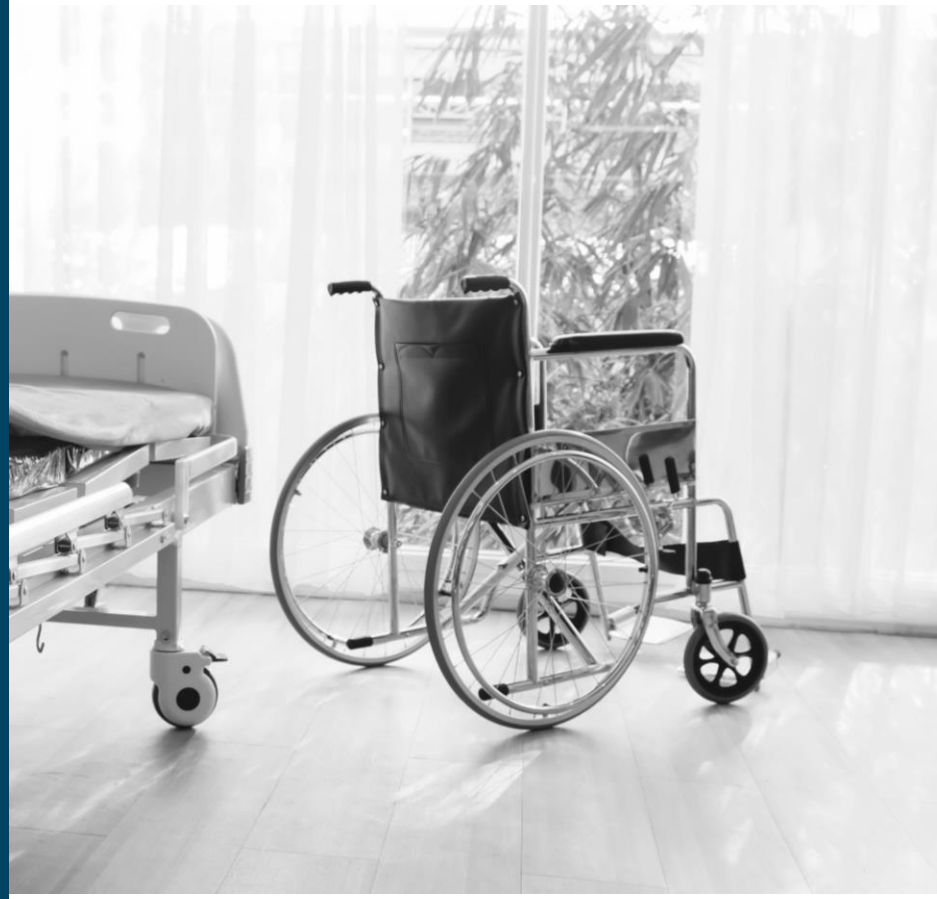
Remote Patient Monitoring



Remote Patient Monitoring

- There is a group of five CPT codes concerning RPM. These codes and their descriptions as specified in the 2021 CPT Professional Codebook ("CPT Codebook") are as follows:
  - 99453: 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.
  - 99454: 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.

Remote Patient Monitoring

- 99457: 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.
- *99458: 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; additional 20 minutes.*
- *99091: 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 healthcare professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days .*

Remote Patient Monitoring

- In order to qualify for CPT code 99454, the medical device supplied must meet the FDA definition of a medical device and should automatically upload the patient data. We understand that the Smart Meter iGlucose meter meets this requirement.
- The 2021 Physician Fee Schedule Final Rule confirmed that RPM services covered by Medicare can only be ordered and billed by physicians or non-physician practitioners (e.g. nurse practitioners [advance practice nurses], physician assistants) who are eligible to bill Medicare for Evaluation and Management services (E/M services). Additionally, this rule confirmed that RPM services can be provided to Medicare patients with acute conditions as well as patients with chronic conditions.

Remote Patient Monitoring

- CPT code 99091 can only be performed by a physician or other qualified healthcare professional. A physician or other qualified healthcare professional is defined in the CPT Codebook 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.”
- When referring to a particular service described by a CPT code for Medicare purposes, a “physician or other qualified healthcare professional” is an individual whose scope of practice and Medicare benefit category include the service and who is authorized to independently bill Medicare for the service.

Remote Patient Monitoring

- CPT codes 99457 and 99458 can be performed by a physician or other qualified healthcare professional, or by clinical staff under the general supervision of the physician.
- General supervision does not require the supervising physician or healthcare professional to be in the same building as the clinical staff member. A clinical staff member is defined in the CPT Codebook as “a person who works under the supervision of a physician or other qualified healthcare professional and who is allowed by law, regulation, and facility policy to perform or assist in the performance of a specified professional service but does not individually report that professional service.” The clinical staff can be provided pursuant to a contract.

Remote Patient Monitoring

- In the 2021 Physician Fee Schedule Final Rule, CMS finalized its proposal to allow auxiliary personnel, in addition to clinical staff, to furnish services described by CPT codes 99453 and 99454 under the general supervision of the billing physician or practitioner.
- Auxiliary personnel include other individuals who are not clinical staff but who are employees or leased or contracted employees.

Remote Patient Monitoring

- A clarification published by CMS on January 19, 2021 found at https://www.federalregister.gov/documents/2021/01/19/2021-00805/medicare-program-cy-2021-payment-policies-under-the-physician-fee-schedule-and-other-changes-to-part regarding billing of CPT codes 99453 and 99454 states “that even when multiple medical devices are provided to a patient, the services associated with all the medical devices can be billed by only one practitioner, only once per patient, per 30 day period, and only when at least 16 days of data have been collected; and that the services must be reasonable and necessary.” This single billing practitioner limitation does not appear to also apply to CPT codes 99457 and 99458.

Remote Patient Monitoring

- In order for RPM services to be covered by Medicare, the following additional requirements must be met:
  - Patient consent must be obtained to provide RPM services.
  - The patient must be an “established patient” of the physician/practitioner billing the RPM services. Medicare considers an “established patient” as one who has received any professional services, i.e., E/M or other face-to-face services, from the physician or group practice within the previous 3 years. See Medicare Claims Processing Manual, Ch. 12, Sec. 30.6.7.
  - The RPM services must be medically necessary.

Remote Patient Monitoring

- CMS has implemented certain modifications to the RPM service requirements on an interim basis for the duration of the COVID-19 PHE. One of these modifications allows RPM services to be provided to a new patient of the RPM practitioner rather than only an established patient.
- CMS made clear in the 2021 Physician Fee Schedule Final Rule that when the COVID-19 PHE ends, it will once again require that RPM services be furnished only to an established patient of the RPM physician.

Remote Patient Monitoring

- In the 2021 Physician Fee Schedule Final Rule, CMS declared that it will permanently adopt the COVID-19 PHE modifications that allow patient consent to be obtained at the time that RPM services are furnished, including having the consent obtained by individuals providing RPM services under contract with the physician/NPP billing for RPM services.

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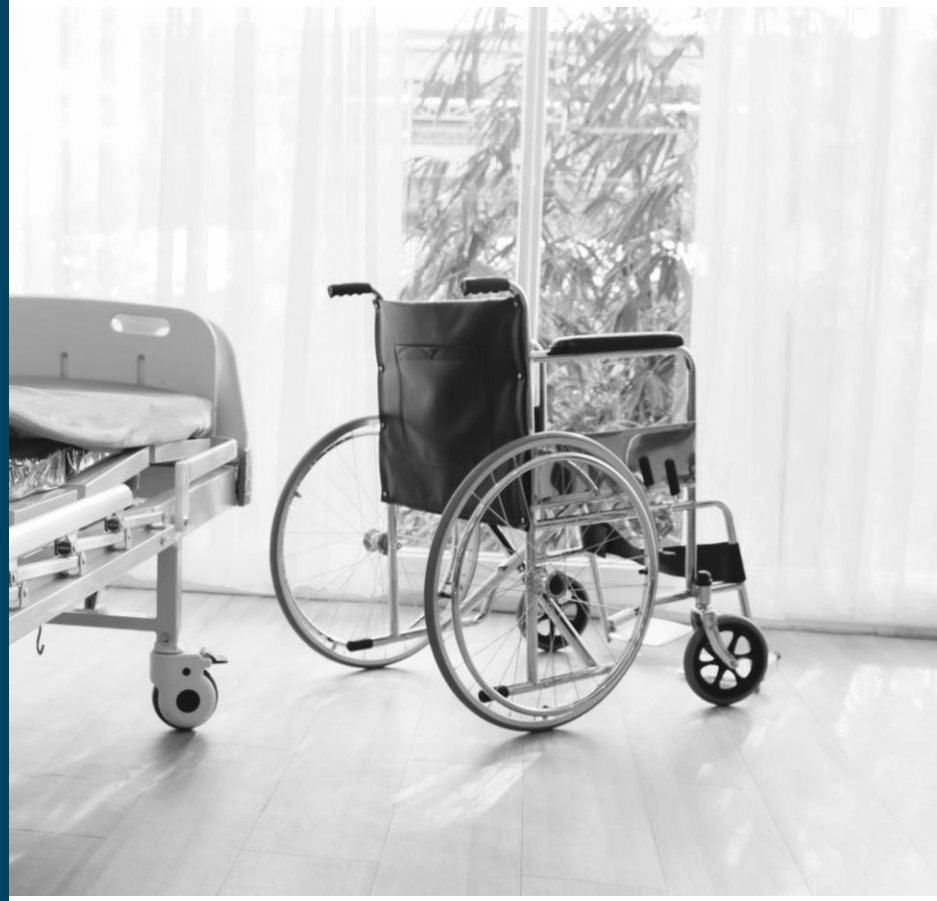
Questions?



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Thank you

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