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The 2021 Medicare Physician Fee Schedule: Remote services and diagnostic testing supervision changes

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The 2021 Medicare Physician Fee Schedule (MPFS) final rule represents one of the last major regulatory changes in the healthcare arena promulgated by the Trump administration.[1] Several of the most significant changes are simply the finalizing on a permanent basis those temporary emergency measures taken in response to the COVID-19 public health emergency (PHE). This article is not intended as an exhaustive examination of all changes within the 2021 MPFS final rule, but rather is a closer exploration of several such changes.

Telehealth and remote services changes

One of the most significant areas to change with the 2021 MPFS is telehealth. Under the Social Security Act, and prior to the COVID-19 pandemic, Medicare would only reimburse telehealth services when they were rendered in eligible geographic areas, including rural health professional shortage areas and counties not classified as metropolitan statistical areas, and only when the patient presented at a physician or other practitioner's office, a federally qualified health center, certain types of hospitals, a community health center, a skilled nursing facility, a renal dialysis center in limited circumstances, or a patient's home in limited circumstances.[2] The service also requires that the technology be an interactive telecommunications system (i.e., not generally a store and forward system). Store and forward technology may be used for patients in Hawaii and Alaska but otherwise is not permitted. Instead, interactive audio and video telecommunications must be used to permit real-time communication between the physician and the patient.[3]

In response to the COVID-19 PHE, however, Congress passed the Coronavirus Aid, Relief, and Economic Security (CARES) Act.[4] Among other things, the CARES Act allowed Centers for Medicare & Medicaid Services (CMS) to waive these geographic and site-of-service requirements, permitting Medicare to reimburse a much broader range of telehealth services than it previously had; patients could now be seen anywhere (including from their homes), and in any geographic locale, including those that did not meet the statutory requirements described above. As of the writing of this article, the PHE remains in effect, and thus, the liberalized telehealth reimbursement provisions also remain in place.

However, once the PHE ends, the liberalizations, including the elimination of the geographic and site-of-service requirements, will also end. CMS explained,

> At the conclusion of the PHE for COVID-19, these waivers and interim policies will expire, payment for Medicare telehealth services will once again be limited by the requirements of section 1834(m) of the [Social Security] Act, and we will return to the policies established through the regular notice and comment rulemaking process, including the previously established Medicare telehealth

> services list, as modified by subsequent changes in policies and additions to the telehealth services list adopted through rulemaking, including in this final rule.[5]

Nevertheless, CMS has exercised its authority to broaden the scope of services that can be performed through telehealth, expanding the scope of covered services. Telehealth services are broken into two broad categories: Category 1 is for services that are similar to office visits, professional consultations, and office psychiatry services; Category 2 is for services that are not similar to those on the current Medicare telehealth services list but which may be requested to be added annually by CMS. Over time, CMS has added to both Category 1 and 2 services, and this continues with the 2021 MPFS final rule. At the end of last year, CMS added nine new codes to the Category 1 services list, including group psychotherapy, prolong evaluation and management services, domiciliary or rest home visits for the evaluation and management of patients, and home visits for the evaluation and management of patients.[6] However, the home, rest home, and domiciliary services will only be available as telehealth services when provided as part of treatment for a substance use disorder or co-occurring mental health disorder, as limited by statutory requirements pertaining to the originating site.

In addition to these expansions, CMS has also created a new Category 3, which will include an even broader range of services, such as those added to the list of eligible telehealth services during the COVID-19 PHE. The new category would allow services to be added to a list on a temporary basis for evaluation and potential addition to Categories 1 or 2 at a later date. CMS explained two general reasons for this new Category 3. First, because the PHE may end before the end of the 2021 calendar year, there may not be enough time during 2021 to develop the type of evidence usually considered when adding services to the telehealth services list on a permanent basis. The second reason, CMS explained, explicitly acknowledged the "extent to which practice patterns are shifting as a result of the PHE…from a model of care based on in-person services to one that relies on a combination of in-person services and virtual care," and CMS recognized that "it would be disruptive to both clinical practice and beneficiary access to abruptly eliminate Medicare payment for these services when furnished via telehealth as soon as the PHE for COVID-19 ends without first providing an opportunity to use information developed during the PHE to support requests for permanent changes to the Medicare telehealth services list."[7] This would permit services added to the Category 3 list[8] to remain on the Medicare telehealth services list for the remainder of the year, even after the PHE has ended.

CMS also finalized a proposed policy to permit physicians to provide direct supervision of incident-to services through telehealth. Specifically, CMS stated, "We are finalizing our proposed clarification that telehealth services may be furnished and billed when provided incident to a distant site physicians' (or authorized NPP's [non-physician practitioner's]) service under the direct supervision of the billing professional provided through virtual presence in accordance with our regulation at" 42 C.F.R. § 410.26 .[9] However, this clarification only applies to *telehealth* services, meaning that it will only be available to rural patients following the end of the PHE or modification of the Social Security Act's telehealth provisions by Congress. Separate from this rule, CMS addressed the provision of direct supervision by interactive telecommunications technology. Initially adopted in response to the PHE, CMS opted to extend the provision that allows a physician to provide direct supervision using interactive audio-video real-time communications technology through the latter of the PHE or the 2021 calendar year. The regulators stated: "The extension of this flexibility would allow time for clinicians to make adjustments and for us to obtain public input on services and circumstances for which this policy might be appropriate on a permanent basis."[10]

Finally, CMS has liberalized the technological requirements for rendering telehealth services. In the past, telehealth services could not be provided through the use of a telephone. Specifically, the regulations at 42 C.F.R.

§ 410.78(a)(3) explicitly prohibited the use of telephones, fax machines, and email for the rendering of telehealth services. Recognizing that this definition was outdated, CMS modernized the language to redefine "interactive telecommunications system" to mean multimedia communications equipment that uses audio and video equipment that can permit two-way, real-time interactive communication between a patient and their physician or other healthcare practitioner.[11] This change will permit the use of a range of devices, including smartphones, tablets, and other devices that meet the definition. However, it is important to remember that CMS lacks the statutory authority to, for example, eliminate the video requirement altogether.

Instead, CMS has created a different category of service, broadly defined as "Communication Technology-Based Services" or "CTBS," which include certain virtual visits performed via telephone when no video component is present. First established in the 2019 MPFS final rule (with the addition of HCPCS code G2012),[12] CMS further expanded the scope of these virtual visits in the 2020 MPFS final rule,[13] and continues this expansion in 2021. From their Healthcare Common Procedure Coding System (HCPCS) descriptions, the new services (HCPCS codes G2251 and G2252) are meant to capture a brief communication, outside the scope of an evaluation and management service, where the virtual check-in itself does not originate from a related evaluation and management service provided within the prior seven days, does not lead to a service or procedure within the next 24 hours or soonest available appointment, and which encompasses roughly five to 20 minutes of medical discussion (i.e., five to 10 minutes for G2251 and 11 to 20 minutes for G2252).[14]

These services will continue beyond the scope of the PHE, but they are intentionally designed to avoid the prohibition on paying for such services as telehealth services because of CMS' interpretation that the Social Security Act requires both audio and video capabilities to reimburse as a telehealth service.

Related to the expansion of telehealth services, CMS also made adjustments to remote physiologic monitoring (RPM). RPM services may continue to be provided to both established and new patients for the remainder of the PHE, at which point they may only be provided to established patients. CMS declined to extend coverage for new patients through the end of the year of the PHE, however. The regulators explained:

> When the PHE for COVID-19 ends, we again will require that RPM services be furnished only to an established patient. We believe that a physician or practitioner who has an established relationship with a patient would likely have had an opportunity to provide a new patient E/M service. During the new patient E/M service, the physician or practitioner would have collected relevant patient history and conducted a physical exam, as appropriate. As a result, the physician or practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RPM services to collect and analyze the patient's physiologic data and to develop a treatment plan.[15]

These changes represent a significant shift in the attitudes toward telehealth and remote services more generally. The statutory provisions that permit telehealth were written in a time when the technology itself was as yet untested and there remained significant concern about the clinical effectiveness of services that were not hands on or at least face-to-face. In the wake of the COVID-19 PHE, however, telehealth has been a necessity. As a result, we now have considerably more data to support the benefit and efficacy of telehealth services. It is therefore no surprise that CMS has liberalized what aspects of telehealth coverage it has the authority to reform.

Nevertheless, CMS' hands are tied by the specific language of the statute; it simply does not have the authority to negate the requirements of the law. Unless and until Congress can pass a law that revises these statutory provisions, telehealth will remain confined primarily to rural settings, in spite of the clear benefit that it offers.

Likewise, CMS has no authority to permit telehealth to be rendered by audio-only services, although it can expand coverage to include virtual check-ins and other remote services like RPM. The changes that CMS has made will be significant also for day-to-day practice for physicians. As the list of available telehealth services grows, the decision to permit physicians and NPPs to remotely supervise other personnel through the use of telehealth technology both for incident-to and diagnostic testing supervision will have profound implications. Physicians rely upon their ability to delegate tasks to subordinates and provide supervision without requiring their personal involvement in every aspect of the service. Prior to these changes, however, telehealth remained one area that required their constant involvement. Now, however, telehealth and other remote services can more closely match the experience of physicians providing services in an office setting. However, until Congress revises the telehealth statutory provisions of the Social Security Act, the revisions applicable to telehealth itself will not last beyond the PHE.

NPP supervision of diagnostic tests

Changes relating to scope of practice represent another significant liberalization in the 2021 MPFS final rule. Under the new regulations, nurse practitioners (NPs), physician assistants (PAs), clinical nurse specialists (CNSs), certified registered nurse anesthetists, and certified nurse midwives (CNMs) may provide supervision of diagnostic testing if they are also permitted to do so under state licensure laws. This represents a significant departure from Medicare's prior stance on this issue and may have larger implications.

These changes were taken by CMS in response to Donald Trump's Executive Order 13890, "Protecting and Improving Medicare for Our Nation's Seniors."[16] As it pertains to the 2021 MPFS final rule, the Executive Order instructed the secretary of the Department of Health & Human Services to propose "a regulation that would eliminate burdensome regulatory billing requirements, conditions of participation, supervision requirements,... and all other licensure requirements of the Medicare program that are more stringent than applicable Federal or State laws require and that limit professionals from practicing at the top of their profession."[17]

In response, CMS sought input from stakeholders to identify Medicare regulations that contain more restrictive supervision requirements than existing state scope-of-practice laws, or which prevented healthcare professionals from practicing at the top of their license (i.e., performing the full range of tasks authorized by their license to the fullest extent permitted by state law). In response, PAs and NPs suggested regulatory changes that would permit them to supervise the performance of diagnostic tests where they are permitted to do so under state law.

Under the Medicare regulations that existed prior to the 2021 MPFS final rule publication, such NPPs were prohibited from supervising the performance of diagnostic testing, regardless of what state licensure laws permitted.[18] While Medicare would reimburse an NPP's *personal performance* of a diagnostic test, the NPP's *supervision* of ancillary personnel was not reimbursable under Medicare's regulations. In one instance, we encountered a Medicare administrative contractor (MAC) that went as far as to state that CPT code 93016 (supervision of cardiac stress testing) could not be performed by an NP *at all*, including personal performance, even when the NP had advanced cardiovascular life support certification. To be clear, the "supervision" in this case is not the supervision of the performance of a diagnostic test by a medical assistant or other clinical staff; it is the supervision of the *patient* as the patient takes the stress test (e.g., runs on a treadmill). Nevertheless, when queried directly about this interpretation, a medical director for the MAC stated that the service could not be reimbursed under Medicare, even if the NP personally performed it.

Based on the response of stakeholders, CMS changed the regulation.[19] The change to the regulations expands the language of 42 C.F.R. § 410.32(b)(1) so that it now also includes language that permits NPs, PAs, CNSs, or

CNMs to supervise diagnostic tests, as permitted by state licensure laws. These provisions had been implemented at the outset of the COVID-19 PHE but have now been made permanent via this regulatory revision.

The change was not met with universal acclaim, however. Among the comments CMS received were those opposing the change, noting that the performance of certain psychological and neuropsychological tests were not within the scope of practice of the NPPs and require special training only available to psychologists and physicians. In response, the regulators noted that this change would mean that such issues would be a matter of state licensure law, rather than CMS policy.[20] Other commenters noted that, while NPPs are vital team members, the teams themselves should remain physician-led, and that the current policy should not extend beyond the COVID-19 PHE, noting that NPPs order more tests and prescribe opioids more than physicians, that patients prefer physicians, and that increasing the supply of NPPs does not increase access to care. In response, CMS stated that it did not find sufficient evidence to support these claims and therefore would proceed with its policy as proposed.[21] The American Medical Association also indicated that it had commented and strongly opposed expanding the scope of practice of NPPs.

This issue represents part of an ongoing battle between physicians and NPP groups, as the NPPs try to expand their scope of practice, while the physicians maintain that NPPs' scope of practice should remain limited, given the differences in training and experience between physicians and NPPs. All of this is set against the backdrop of a country with an aging baby boomer population, increased demand for physicians, and a physician shortage. In the midst of these battles, CMS has, at least with respect to supervision of diagnostic testing, effectively withdrawn from the fight, allowing the matter to be resolved at the state level. In other words, if state law permits the NPP to supervise a diagnostic test, Medicare will reimburse the service.

NPPs will still need to work in conjunction with physicians in accordance with state law; for NPs this usually takes the form of a collaboration agreement, while with PAs it is a supervisory relationship with the physician. The regulators acknowledge this fact, at least with respect to NPs and CNSs. The regulators stated, parenthetically, "We noted that, as for all services furnished by a NP or CNS, they would have to be furnished working in collaboration with a physician as provided in regulations at §§ 410.75 and 410.76, respectively."[22]

To date, Executive Order 13890 has not been revoked by President Biden. Although that possibility remains, it seems unlikely for the foreseeable future, at least with respect to the top-of-license issues. The impact of this regulatory change will be to further empower NPPs and permit those practices that make use of them to expand the range of services that their NPPs may perform. The NPPs will still be paid at a reduced rate by Medicare compared to a physician (most NPPs are paid at 85% of the MPFS rate for the same service), so there is still an incentive for physicians to provide supervision where possible (itself made easier, thanks to the remote supervision changes discussed above).

Conclusion

In the wake of the COVID-19 pandemic, the healthcare industry has had to make many rapid changes, resulting in a shift in attitudes toward old stances such as skepticism about the clinical value of telehealth services and how much authority may be granted to NPPs. Federal regulators have taken what legally permissible steps they can to expand telehealth services without further action from Congress. They have also left it to the states to determine whether NPP scope of practice will include supervision of diagnostic testing. In each case, though, regulatory hurdles still remain, and healthcare providers will need to ensure that they remain compliant with these new requirements after the PHE ends. Experienced legal counsel can help.

Takeaways

- Centers for Medicare & Medicaid Services has broadened the scope of services that can be performed through telehealth.
- Physicians and nonphysician practitioners can now supervise incident-to services through telehealth.
- Only Congress can fully revise the statutory requirements for telehealth services.
- Nonphysician practitioners can now supervise diagnostic testing; previously, only physicians could.
- Nonphysician practitioners must still work with physicians in accordance with state laws.

1 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Quality Payment Program; Coverage of Opioid Use Disorder Services Furnished by Opioid Treatment Programs; Medicare Enrollment of Opioid Treatment Programs; Electronic Prescribing for Controlled Substances for a Covered Part D Drug; Payment for Office/Outpatient Evaluation and Management Services; Hospital IQR Program; Establish New Code Categories; Medicare Diabetes Prevention Program (MDPP) Expanded Model Emergency Policy; Coding and Payment for Virtual Check-in Services Interim Final Rule Policy; Coding and Payment for Personal Protective Equipment (PPE) Interim Final Rule Policy; Regulatory Revisions in Response to the Public Health Emergency (PHE) for COVID-19; and Finalization of Certain Provisions from the March 31st, May 8th and September 2nd Interim Final Rules in Response to the PHE for COVID-19, 85 Fed. Reg. 84,472 (December 28, 2020) , http://bit.ly/3dLJhfG.
2 42 U.S.C. § 1395m(m) .
3 Centers for Medicare & Medicaid Services, "Chapter 12 - Physicians/Nonphysician Practitioners," § 190.4, *Medicare Claims Processing Manual*, Pub. 100-04, revised July 25, 2019, https://go.cms.gov/3cYj5Q4.
4 Coronavirus Aid, Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (2020).
5 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,507 .
6 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,504–84,505 .
7 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,507 .
8 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,511–84,516 .
9 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,537–84,538 .
10 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,538 .
11 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 85,027 .
12 Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, 83 Fed. Reg. 59,452, 59,482–59,486 (November 23, 2018) , https://bit.ly/3dqRK9c.

13 Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations Final Rule; and Coding and Payment for Evaluation and Management, Observation and Provision of Self-Administered Esketamine Interim Final Rule, 84 Fed. Reg. 62,568, 62,795–62,796 (November 15, 2019) , https://bit.ly/3dpd27h.
14 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,532 .
15 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,544 .
16 Protecting and Improving Medicare for Our Nation's Seniors, 84 Fed. Reg. 53,573 (October 8, 2019) .
17 Protecting and Improving Medicare for Our Nation's Seniors, 84 Fed. Reg. 53,574 .
18 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,590–84,591 .
19 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,591 .
20 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,591 .
21 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,591 .
22 Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 85 Fed. Reg. 84,591 .