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TELEHEALTH EXPANSION: PROPOSED 2021 PHYSICIAN FEE SCHEDULE UPDATES AND PLANNING FOR THE NEW NORMAL

The COVID-19 state of emergency has spurred unprecedented change in the realm of telehealth. This trend continues – but despite the headlines, there is more work to do.

I. CMS TELEHEALTH PROPOSALS CY 2021 PFS

On August 3, 2020, CMS posted the proposed Physician Fee Schedule rule ("Proposed Rule") for CY 2021. The Proposed Rule includes some limited telehealth expansion as well as a proposal to permit continued use of interactive telecommunication for supervision via virtual presence. Comments will be due 60 days from publication of the Proposed Rule in the Federal Register.

Proposed Telehealth Additions:

Category 1: Services added on a Category 1 basis are similar to services already on the telehealth list. For CY 2021 CMS is proposing to add HCPCS codes related to visit complexity, prolonged visits, group psychotherapy, neurobehavioral status exam, cognitive impairment care planning, rest home/custodial care visits and home visits. The specific codes and descriptions can be found on the CMS Fact Sheet.

Category 3: Category 3 is being proposed as a temporary category to describe services added to the Medicare telehealth list during the public health emergency ("PHE") for the COVID-19 pandemic. Category 3 services will only remain on the telehealth list through the calendar year in which the PHE ends. CMS is proposing to add HCPCS codes related to rest home/custodial care visits and home visits that describe different services from the proposed Category 1 services. Further, CMS is proposing to add ED visits, nursing facility discharge day management and psychological and neuropsychological testing as temporary Category 3 services. The specific codes and descriptions can be found on the CMS Fact Sheet. CMS is soliciting public comments on the current list of services temporarily added to the Medicare telehealth list during the PHE that CMS is not proposing to add permanently, or proposing to only add temporarily on a Category 3 basis.

Proposed Direct Supervision via Interactive Telecommunication:

Currently, during the PHE, CMS permits direct supervision, for incident to services and other diagnostic services requiring that level of supervision, to be provided via the virtual presence of a supervising physician or practitioner using interactive audio/video real-time communications technology (85 FR 19245). For CY 2021, CMS is proposing to allow direct supervision to be provided in this manner, that is using real-time, interactive audio and video technology (excluding telephone only) through December 31, 2021. CMS is seeking public comments regarding patient safety and clinical appropriateness as well as any potential concerns related to induced utilization and fraud, waste and abuse.

Policy Clarification:

In the Proposed Rule, CMS clarifies that licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists and speech-language pathologists can furnish brief online assessment and management services as well as virtual check-ins and remote evaluation services. Further, CMS clarifies that the Medicare telehealth rules do not apply when a physician or other practitioner furnishes a service to a beneficiary using audio/video technology if the physician/practitioner and beneficiary are in the same location.

II. PLANNING FOR THE NEW NORMAL

The proposed updates to the Physician Fee Schedule, discussed above, follow HHS's recent study evidencing the dramatic increase in telehealth utilization. Last week, on July 28, HHS released a new report focusing on telehealth services for primary care delivery during the initial months of the pandemic. A copy of the press release, which contains a link to this study, can be found here.

The report finds a nearly 50% increase in the use of telehealth during the pandemic (from January to June 2020). The study noted a more substantial increase in urban areas as opposed to rural settings. This is not surprising given that urban settings largely did not qualify as eligible "originating sites" for purposes of Medicare reimbursement prior to the initial round of COVID 19-related waivers.

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The report also anticipates a greater demand for telehealth – by both practitioners and patients – following the pandemic. This is also not surprising. The COVID-19 state of emergency has spurred unprecedented change in the realm of telehealth and telemedicine (collectively "virtual care").

Many of the traditional obstacles to practicing through virtual care (licensure, reimbursement, HIPAA, etc.), which do not directly bear on its efficacy, have been temporarily removed (or relaxed) through various state and federal waivers, exceptions or enforcement discretion. These exceptions have enabled providers of all types to launch virtual care solutions – from large urban health systems to individual rural providers.

Despite this progress, and despite the headlines, there is still considerable work to be done. The majority of these waivers and exceptions still have a defined life span – the designated period of emergency or until revoked by the applicable agency. Legislative change is still required to make these exceptions, or some portion of them, permanent. Lawmakers are expected to pursue telehealth related legislation in the next health-focused legislative package, at the minimum to extend the existing telehealth waivers beyond the PHE.

Additionally, the bulk of these changes relate specifically to Medicare reimbursement. These exceptions do not address the state-specific requirements for virtual care, which are highly variable, and which creates a significant barrier to intrastate and interstate virtual care practice.

In this context, health care providers who intend to utilize virtual care in the longer term should consider the following:

Professional Licensure:

Many states have implemented licensure exceptions as a result of COVID-19. The extent of these exceptions, associated limitations and application to various provider-types is highly variable. Providers who are utilizing these current licensure exceptions, especially those providing virtual care services in multiple states, should be mindful of this variability and the impending expiration. These providers should begin to consider more permanent licensure options state to state in order to maintain their virtual care practice.

Scope of Practice:

As with licensure, the applicable exceptions are highly variable in application to different provider types. For example, collaboration/supervision requirements applicable to APRNs and PAs differ; therapy standards differ; psychology and behavioral health standards differ, etc. In addition to this variability, many states have failed to address, in one way or another, the ability to practice through virtual care. While the current exceptions generally provide a fair amount of flexibility, as we emerge from the period of emergency, health care providers will need to pay close attention to these practice standards, state-to-state, and ensure their virtual care practice is both permissible and compliant.

Prescriptive Practices:

The DEA's current emergency exception to permit the prescription of controlled substances through synchronous audio/visual will end with the state of emergency. Absent the DEA issuing rules to permit the long-awaited "special registration" for virtual care, the Ryan Haight Act will once again dictate the approach – meaning a prior in-person examination will be required prior to the prescription of a controlled substance unless one of the Act's narrow exceptions for telehealth are available. Many states have also enacted exceptions to facilitate the prescription of medications through virtual care – even for chronic pain management in certain jurisdictions. Providers now using virtual care as part of their current practice should be in a position to modify current work-flows and adjust to the much more restrictive pre-COVID 19 rules for prescriptions.

Informed Consent and Acknowledgement of Financial Responsibility:

Given the quick ramp-up of virtual care, as well as the increased opportunity to see new patients through virtual care, many providers have not been in a position to obtain written informed consent. With the move to a more permanent virtual care practice, providers should consider the different options to obtain written/signed consent and acknowledgment of financial responsibility and also should pay particular attention to the content of that form. While verbal consent is often (but not always) sufficient to meet various statutory and reimbursement requirements, a written/signed consent form is hugely beneficial to document compliance with various consent discussion elements state to state. Additionally, providers should note that verbal consent is not always sufficient. Different specialties (such as psychologists) are

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required by their respective governing boards to obtain written consent, which contains particular elements. Providers should also consider implications and workflows attendant to obtaining minor consent.

Reimbursement:

As discussed above, an enormous change has occurred in relation to telehealth reimbursement during the PHE. Medicare paved the way, largely by waiving its highly restrictive originating site requirements and expanding the list of eligible telehealth services. Medicaid in most states has followed suit, in many instances also vastly expanding the use of audio-only services. Many commercial payors have made similar changes. While there is a clear stakeholder push to make permanent changes to Medicare coverage and reimbursement for telehealth services, it remains to be seen what permanent changes, if any, will be made to Medicare services as well as state Medicaid programs and commercial payors. As the COVID-19 exceptions and waivers expire, providers will need to understand the implications for their virtual care practice and be in a position to adjust accordingly.

HIPAA:

During the state of emergency, OCR has announced it will not enforce penalties for HIPAA violations in instances where providers are using a non-public facing platform (such as FaceTime or Skype) in good faith to render virtual care services, even though the platform is non-HIPAA compliant. Many providers (and patients) have taken advantage of these widely used modalities to quickly convert to virtual care. The ability of providers to utilize these communication tools will cease when OCR determines that the facts and circumstances no longer merit the exercise of the enforcement discretion. Providers should ensure that no patient data is stored in or remains in non-HIPAA compliant systems. It would be prudent for providers to identify and migrate to a telemedicine platform that enables continued provision of virtual care services consistent with the requirements of HIPAA.

Medical Records:

The pandemic prompted many providers to quickly adopt telehealth platforms to facilitate the delivery of virtual care without the opportunity to carefully consider how patient virtual encounter information would be incorporated into the existing patient medical records. Some telehealth platforms include questionnaires or other documentation functions that facilitate the encounter and hold a portion of the designated record set. The newly released Information Blocking Regulations will obligate health care providers to make such information available to patients and their proxies upon request. Information retained in secondary telemedicine platforms can create challenges for healthcare providers responding to a request for patient access or an allegation of information blocking. Providers should carefully review their workflow to ensure that all information necessary to support the treatment decisions made as a result of the encounter are incorporated into the patient medical record and determine to what extent data maintained within a telemedicine platform is subject to the scope of the Information Blocking Regulations.

Funding Opportunities:

We have already seen, and expect we will see more, availability of FEMA, USDA, HRSA and FCC funding to acquire telemedicine equipment. Providers will want to remain vigilant regarding these opportunities. The funding is typically limited and there are numerous applicants. Submitting an application that is timely and complete is often key. The funding programs generally include reporting, record retention and audit obligations. Providers should ensure that they continue to comply with any conditions related to use, resale, repurposing of equipment and services funded through these programs. In addition, providers should ensure that they maintain records sufficient to comply with any audit rights of the granting agency, funding administrator or OIG. Finally, providers should ensure that they have entered into appropriate agreements memorializing the further distribution of grant or program funds or equipment.

Legal Compliance:

The current COVID-19 related exceptions have assisted providers to appropriately navigate the implications of the federal Stark law, Anti-Kickback Statute and Civil Monetary Penalty law in order to cooperate and share resources through a broad array of arrangements that may have otherwise been prohibited. As the applicable exceptions expire, we anticipate that providers may be required to un-wind certain arrangements. It would prudent for providers to take inventory of their relevant compensation and remuneration transactions in order to consider whether and how such arrangements may continue to operate in the absence of the COVID-19 exceptions. Such action may include the clarification that virtual care equipment was lent only for the term of the emergency or otherwise gifted permanently. Those transactions

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that cannot be amended to be compliant without the applicable exceptions will need to be timely terminated. As always, appropriate documentation of such matters will be critical.

If you have additional questions, please contact:

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Hall Render's attorneys and professionals continue to maintain the most up-to-date information and resources at our COVID-19 Resource page, through our 24/7 COVID-19 Hotline at (317) 429-3900 or by contacting your regular Hall Render attorney.

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