Morgan Lewis | White Paper

COVID-19: CMS ISSUES NEW POLICY CHANGES FOR A PHASED REOPENING OF THE COUNTRY

May 2020

www.morganlewis.com

COVID-19: CMS ISSUES NEW POLICY CHANGES FOR A PHASED REOPENING OF THE COUNTRY

The Centers for Medicare & Medicaid Services (CMS) released a second, sweeping interim final rule (IFR) in response to the coronavirus (COVID-19) pandemic on April 30, 2020. Building on the agency's unprecedented March 31, 2020 regulation, which prioritized distancing patients from their care teams in response to the public health emergency (PHE), this second round of policy changes emphasized easing COVID-19 testing restrictions and expanding health system capacity for a phased reopening of the country.

According to CMS, the April 30 IFR was informed by requests from healthcare providers and in response to the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Some of the regulations in the IFR also address a previous interim final rule with comment, which appeared in the April 6, 2020 *Federal Register* with an effective date of March 31, 2020 (March 31 rule), and that Morgan Lewis analyzed in a previous White Paper.

The IFR comprises numerous policy changes that affect the full spectrum of healthcare settings, services, and provider types. Highlights from the IFR include enhancing access to diagnostic testing, extending hospital and health system capacity via temporary expansion sites, augmenting the healthcare workforce, expanding flexibility for telehealth services, adjusting the Medicare Shared Savings Program, and further reducing administrative burdens and requirements on an interim basis.

CMS has released new blanket waivers and a slew of updated provider-specific fact sheets in connection with the IFR. The agency has also issued FAQs that clarify hospital EMTALA obligations during the PHE.

The policies in the IFR are effective retroactive to March 1, 2020 or January 27, 2020, and are applicable during the declared PHE period, with certain exceptions. Comments to the IFR must be received no later than 5:00 pm ET on July 7, 2020.

Below we outline every provision of the IFR. Providers should remember that, after reviewing these provisions, they may need to adjust prior claims to comply with CMS's billing instructions. Morgan Lewis stands ready to assist healthcare providers in understanding and implementing CMS's policy changes to Medicare and Medicaid programs in response to the COVID-19 PHE.

A. Reporting Under the Home Health Value-Based Purchasing Model for Calendar Year 2020 During the PHE

The IFR proposes to align the Home Health Value-Based Purchasing (HHVBP) model data submission requirements with any exceptions or extensions granted for purposes of the Home Health Quality Reporting Program (HHQRP) during the PHE. This applies to those home health agencies (HHAs) participating in the model and essentially aligns HHQRP data reporting for HHAs whether or not they are in the model program. CMS will also implement a policy to grant exceptions for new measure data reporting requirements during the PHE. It is CMS's intention to ensure that extensions for quality data reporting are the same for HHAs whether they participate in the model program or not.

If CMS grants an exception or extension under the HHQRP that either excepts HHAs from reporting certain quality data altogether, or otherwise extends the deadlines by which HHAs must report those data, the same exceptions and/or extensions apply to the submission of those same data for the HHVBP model. Notably, Home Health Outcome and Assessment Information Set (OASIS) reporting remains unchanged except for the PHE time extensions previously granted.

Presently, CMS has excepted HHAs from the requirement to report any HHQRP data for the following quarters:

- October 1, 2019 to December 31, 2019 (Q4 2019)
- January 1, 2020 to March 31, 2020 (Q1 2020)
- April 1, 2020 to June 30, 2020 (Q2 2020)

Additionally, to ensure that HHAs are able to focus on patient care instead of data submission requirements during the PHE, CMS intends to grant exceptions to new measure reporting for HHAs participating in the HHVBP model during the PHE. These changes will be codified at Section 484.315(b). The current new measure reporting requirements under the IFR are:

- April 2020 new measures submission period (data collection period is October 1, 2019 to March 31, 2020)
- July 2020 new measures submission period (data collection period is April 1, 2020 to June 30, 2020)

CMS has acknowledged that the COVID-19 pandemic will skew performance data for the HHVBP model and other data reporting, and it is evaluating possible changes to home health payment methodologies for calendar year (CY) 2022. Future rulemaking in this regard is anticipated and interested stakeholders should closely monitor developments in this area.

B. Scope of Practice

Supervision of Diagnostic Tests by Certain Nonphysician Practitioners

In seeking to allow greater flexibility, CMS will temporarily allow physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), certified nurse midwives, and other nonphysician practitioners to supervise the performance of diagnostic tests, subject to applicable state law, during the PHE.

Therapy – Therapy Assistants Furnishing Maintenance Therapy

CMS will permit occupational therapy assistants or physical therapy assistants to perform maintenance therapy when clinically appropriate.

Therapy – Student Documentation

On an interim basis during the PHE, the billing clinician may review and verify (sign and date), rather than redocument, information added to the medical record by any member of the healthcare team.

Pharmacists Providing Services Incident to Physicians' Services

CMS will allow pharmacists to provide services incident to the services, and under the appropriate level of supervision, of a billing physician or nonphysician practitioner (NPP), if payment for the services is not made under the Medicare Part D benefit.

C. Modified Requirements for Ordering COVID-19 Diagnostic Laboratory Tests

During the PHE, CMS is making COVID-19 testing, including testing for antibodies, available without a physician's order, so long as the test is ordered by a professional licensed under state law to do so, such as a pharmacist. Additionally, as symptoms of the flu and respiratory syncytial virus are similar to those of COVID-19, CMS is also waiving the physician's order requirement for these tests when they are ordered in conjunction with COVID-19 testing. What is not clear is whether a patient needs to be symptomatic when they get tested, or whether they can have multiple, prophylactic tests without a physician's order.

D. Opioid Treatment Programs – Furnishing Periodic Assessments via Communication Technology

As noted in our White Paper on the March 31 rule, CMS revised 42 CFR § 410.67 regarding Medicare coverage of and payment for opioid use disorder treatment services furnished by opioid treatment programs (OPTs) to ensure that beneficiaries with opioid use disorders can continue to receive these important services during the COVID-19 PHE. Specifically, 42 CFR §§ 410.67(b)(3) and (4) were revised to allow the therapy and counseling portions of the weekly bundles of services, as well as the add-on code for addition therapy or counseling, to be furnished using audio-only telephone calls in situations where beneficiaries do not have access to two-way interactive audio-video communication technology.

In the IFR, CMS made corresponding changes to 42 CFR § 410.67(b)(7) on an interim final basis to allow periodic assessments by OTPs, which are addressed by a new add-on code (HCPCS code G2077) created in the CY 2020 Physician Fee Schedule (PFS) final rule, to be furnished during the PHE using two-way interactive audio-video communication technology. As with the therapy and counseling services, periodic assessments also may be furnished using audio-only telephone calls in instances where beneficiaries do not have access to interactive audio-video technology, provided all other applicable requirements are met. CMS notes that if in an OTP's clinical judgment a periodic assessment cannot be adequately performed over an audio-only call, it expects the assessment will be performed using two-way interactive audio-video communication technology or in person as clinically appropriate.

Finally, the IFR reminds states that the Substance Abuse and Mental Health Administration (SAMHSA) at the US Department of Health and Human Services has provided guidance and resources to help individuals, providers, and communities across the country confront the challenges posed by the PHE, including flexibilities to states to ensure that individuals being treated with medication for opioid use disorders can continue to receive their medication.

E. Treatment of Certain Relocating Provider-Based Departments During the PHE

CMS is allowing provider-based clinics to relocate to new off-campus locations and maintain their "grandfathered" status that allows them to be paid at the full hospital outpatient rate. Prior to the pandemic, CMS allowed relocations only in emergency circumstances, which require CMS Regional Office approval. However, for the duration of the PHE, it will allow relocations (both for on-campus sites and off-campus sites) to new off-campus locations by providing notice to the CMS Regional Office that includes an explanation of the need and an attestation that the move is not inconsistent with the state's emergency preparedness or pandemic plan. Importantly, hospitals will need to plan how to move these clinics back to their original location before the PHE expires, or face the loss of their grandfathered status.

The relocation flexibility extends to the number of sites to which a hospital can relocate a clinic. One site can be relocated to multiple other locations. A site can also be relocated to a patient's home, and once a hospital opts to call a patient's home a grandfathered provider-based site, it can treat all patient homes as provider-based at the same time. Further, a site does not need to fully relocate. Rather, it can continue to furnish grandfathered, provider-based services at its original site, as well as at its new site. No enrollment of the new site is necessary.

F. Furnishing Hospital Outpatient Services in Temporary Expansion Locations of a Hospital or Community Mental Health Center (Including a Patient's Home)

As a follow-on to CMS's issuance of waivers to allow hospitals to furnish hospital services in nontraditional places, such as patients' homes, CMS has eased certain payment requirements to allow for payment in these locations.

CMS has broken the types of services that might be furnished in these locations into three categories:

- Outpatient therapy, education, and training services that are typically furnished by someone other than a physician and can be performed from a distance
- In-person services furnished at a temporary expansion location
- Hospital services associated with a professional service delivered via telehealth

As to outpatient therapy, education, and training services, CMS is allowing hospitals to receive payment for these services when provided through telemedicine, so long as the patient is in the "hospital" (which can include the patient's home), the patient is registered as an outpatient, and the requisite level of supervision has been met.

For hospital services that are furnished in person but do not require a professional service, such as wound care or drug administration, CMS is also allowing hospitals to bill for these services when furnished in nontraditional spaces. As with any other hospital outpatient service, they must be furnished to an outpatient, in a space considered part of the "hospital," and under the appropriate level of supervision.

For professional services rendered via telehealth to expansion sites, CMS is allowing hospitals to bill the originating site facility fee. CMS does not expressly address how payments are to be determined when a patient actually presents at the hospital and receives services via telehealth once there. One reading of the IFR would dictate that even here, all that a hospital is entitled to is the originating site facility fee. As this would be substantially lower in some cases than for other similarly situated patients, where the only difference is whether the physician furnished services in person or via telehealth, hospitals may wish to submit comments to object to this policy.

G. Medical Education

Indirect Medical Education

CMS recognizes that the dramatic expansion of hospital capacity to address potential surges relating to COVID-19 patient populations may have unintended consequences on a hospital's reimbursement for its indirect medical education (IME) costs. The IME payment formula is derived from a ratio of the number of the hospital's full-time equivalent (FTE) interns and residents to the number of the hospital's available beds. Hospitals needing to expand their bed capacity to prepare for the surge (or potential surge) of COVID-19 patients would see their IME reimbursements decline over the applicable cost reporting period because of the increase in the denominator of the intern resident bed (IRB) ratio due to the PHE.

Likewise, inpatient rehabilitation facilities (IRFs) and inpatient psychiatric facilities (IPFs) receiving "teaching status adjustments" are paid on a ratio that takes into account the number of FTE interns and residents divided by the average daily census (subject to a cap). These facilities also face concerns with the reduction of their teaching status payments due to increases in their average daily census because they are making space available in acute care settings for COVID-19 patients.

In the IFR, CMS has adopted a rule "holding harmless" these providers for these COVID-19-related facility bed-size and census changes. For purposes of the IME adjustment, hospitals will be considered to have the number of available beds in place on the day before the PHE declaration, and any changes during the PHE period (January 27, 2020 through any subsequent renewal of the PHE) would not be included in calculating a hospital's IME payment adjustment. IRFs and IPFs will also be held harmless and paid in accordance with the teaching status adjustments that were effective as of the day before the PHE declaration.

Graduate Medical Education

The Medicare payment for direct Graduate Medical Education (GME) is calculated based on an updated base-year average per-resident cost multiplied by the number of weighted full-time residents for the current cost reporting period. Typically, to be counted, the time spent by FTE residents must be spent in the hospital complex of the hospital claiming the GME payment.

Recognizing that teaching hospitals may need to share their residents with other hospitals to expand a community's capacity during the PHE, CMS also established a protection for GME payments. According to the IFR, a hospital may include residents in its FTE count for GME (and IME) purposes during the PHE even if a resident is training at another hospital site, provided the following conditions can be met:

- The sending hospital sends the resident to another hospital in response to the COVID-19 pandemic. This criterion would be met if either the sending hospital or the other hospital were treating COVID-19 patients without regard to whether the resident is involved with COVID-19 patients.
- Time spent by the resident at the other hospital would be considered to be time spent in approved training if the activities performed by the resident at the other hospital were consistent with non-PHE guidance.
- The time that the resident spent training immediately prior and/or subsequent to the timeframe that the PHE associated with COVID-19 was in effect was included in the sending hospital's FTE resident count.

These conditions will require some documentation to support the inclusion in the FTE count for the cost reporting year(s) at issue, and teaching hospitals are advised to review their practices and incorporate any documentation that would support making cost reporting claims for FTEs sent to other hospitals during the PHE. As noted, above, this protection, and the conditions with it, apply to the FTE count for the IME adjustment as well.

H. Rural Health Clinics

CMS is changing on an interim basis the periods of time used to determine the number of beds in a hospital at Section 412.105(b) for purposes of determining which provider-based rural health clinics (RHCs) are subject to the payment limit. To that end, CMS will use the number of beds from the cost reporting period prior to the start of the PHE as the official hospital bed count for application of this policy.

As a result, RHCs with a provider-based status that were exempt from the national per-visit payment limit in the period prior to the effective date of the PHE (January 27) will continue to be so exempt for the duration of the COVID-19 PHE.

I. Durable Medical Equipment Interim Pricing in the CARES Act

CMS discusses the implementation of Section 3712 of the CARES Act, which revises the fee schedule amounts for certain durable medical equipment (DME) and enteral nutrients, equipment, and supplies furnished in rural and other noncompetitive bidding areas through the duration of the PHE.

CMS advises that it will extend the 50/50 blended rate for rural suppliers through the later of December 31 or the end of the PHE. CMS notes ambiguities in the law regarding the effective date of the increased rates, and affirms that in order to aid suppliers in furnishing items, the 75/25 blended rates for nonrural, noncompetitive bid areas will be implemented beginning March 6, 2020.

J. Care Planning for Medicare Home Health Services CMS-5531-IFC 9

Retroactive to March 1, 2020, the IFR implements the CARES Act directive to allow physician extenders such as NPs, CNSs, and PAs to order and certify patients for eligibility under the Medicare home health benefit and to allow these skilled medical professionals, consistent with state law scope of practice, to establish and periodically review the home health plan of care. The IFR conforms this change to other provisions such as authorizing payment for the furnishing of items and services under the home health prospective payment system (HHPPS) when these items and services are prescribed by an NP, CNS, or PA. Notably, the IFR also suspends the Administrative Procedure Act (APA) notice and comment period for conforming this change to the home health provider enrollment rules contained in Section 424.507.

CMS expressed this action as "imperative" during the PHE as more beneficiaries may be considered "homebound" under its expanded definition. CMS has astutely recognized that homebound can mean a practitioner has determined that it is medically contraindicated for a patient to leave the home because he or she has a confirmed or suspected diagnosis of COVID-19, or because a practitioner has determined that it is medically contraindicated for a patient to leave the home because the patient has a condition that may make the patient more susceptible to contracting COVID-19.

The expansion of nonphysician extender clinical supervision is subject to varying state law requirements and many states require physician collaboration for NPs. CMS expresses the view that these professionals may practice to the top of their licensure authority but in full compliance with state laws.

Finally, for Medicare home health purposes, relevant regulations are amended to include NP, CNS, and PA practitioners as "allowed practitioners." This means that in addition to a physician, as defined in Section 1861(r) of the Social Security Act, an "allowed practitioner" may certify, establish, and periodically review a patient's plan of care, as well as supervise the provision of items and services for beneficiaries under the Medicare home health benefit. The IFR confirms that allowed practitioners may now also perform the face-to-face encounter with a patient for whom they are certifying eligibility; however, if a face-to-face encounter is performed by an allowed NPP in an acute or post-acute facility, from which the patient was directly admitted to home health, the certifying practitioner may be different from the provider performing the face-to-face encounter. These policy changes are permanent and are not time limited to the period of the PHE.

As noted in prior commentary, these regulatory changes are transformational for home health services provided to the Medicare and Medicaid populations in recognition of the advanced clinical skills of these professionals, but also dramatically increase need for home health services under the expanded concept of homebound.

K. Clarification of CARES Act Waiver of the Three-Hour Rule for IRFs During the PHE

CMS provided a clarification regarding the CARES Act waiver of Section 412.622(a)(3)(ii) during the emergency period, recognizing CMS's March 31 rule was mooted by the CARES Act's specific waiver language. The waiver required by Section 3711(a) of the CARES Act is not limited to particular IRFs or patients, and therefore is available during the emergency period described in Section 1135(g)(1)(B) of the act regardless of whether a patient was admitted for standard IRF care or to relieve acute care hospital capacity. CMS also sought to recognize the differences between distinct part IRF units and IRFs that are freestanding.

Per the IFR, CMS incorporated the White House Guidelines for Opening Up America Again for the purposes of exercising the regulatory relief, providing broad flexibility for freestanding inpatient rehabilitation facility hospitals to provide surge capacity in support of acute care hospitals in their state or community. CMS considers surge to be alleviated with regard to exercising the waiver flexibilities when the state (or region, as applicable) in which the freestanding IRF is located is in phase 2 or phase 3 of the

White House guidelines. In other words, the flexibilities in the IFR are available for freestanding IRFs admitting patients in support of acute care hospitals when the state is in phase 1 or prior to entering phase 1, but are no longer available to the freestanding IRFs when the state is in phase 2 or phase 3 of the guidelines. The waiver flexibilities apply to specific patients who must be discharged from the acute care hospitals to the freestanding IRFs to provide surge capacity for the acute care hospitals, and therefore apply only when those specific patients are admitted to the freestanding IRFs and continue for the duration of the patients' care.

For billing purposes, CMS is requiring freestanding IRFs to append the "DS" modifier to the end of the IRF's unique patient identifier number (used to identify the patient's medical record in the IRF) to identify patients who are being treated in a freestanding IRF solely to alleviate inpatient bed capacity in a state that is experiencing a surge during the COVID-19 PHE. The modifier will be used to identify those patients for whom the requirements in Section 412.622(a)(3)(i), (iii), (iv), (4) and (5) do not apply. Freestanding IRFs will be paid at the IRF PPS rates for patients with the "DS" modifier.

To effectuate these changes, CMS is making amendments to Section 412. 622(a)(3)(i), (ii), (iii), and (iv) to state that these IRF coverage criteria continue to be required, except for care furnished to patients in a freestanding IRF solely to relieve acute care hospital capacity in a state (or region, as applicable) that is experiencing a surge during the PHE. CMS also amended the documentation requirements with respect to such patients. Freestanding IRFs should take care to identify and document the patients they are accepting to relieve acute care hospitals to ensure that they can take advantage of these regulatory flexibilities.

L. Medicare Shared Savings Program

CMS has implemented changes to the Shared Savings Program to encourage continued participation by accountable care organizations (ACOs) by adjusting program policies as necessary to address the impact of the COVID-19 pandemic. CMS is increasing flexibility to ensure that ACOs are treated equitably regardless of the degree to which their assigned beneficiary populations are affected by the pandemic.

CMS is making the following modifications:

- For those ACOs that entered a first or second agreement period with a start date of January 1, 2018, they may elect to extend their agreement period for an optional fourth performance year. However, the election to extend the agreement period is voluntary and an ACO could choose not to make this election, and therefore conclude its participation in the program with the expiration of its current agreement period on December 31, 2020. Additionally, CMS is allowing ACOs in the BASIC track's glide path the option to elect to maintain their current level of participation for person year (PY) 2021. Prior to the automatic advancement for PY 2021, an applicable ACO may elect to remain in the same level of the BASIC track's glide path that it entered for PY 2020. For PY 2022, an ACO that elects this advancement deferral option will be automatically advanced to the level of the BASIC track's glide path in which it would have participated during PY 2022 if it had advanced automatically to the next level for PY 2021 (unless the ACO elects to advance more quickly before the start of PY 2022).
- CMS provided necessary clarification that in regard to the Shared Savings Program, the months affected by an extreme and uncontrollable circumstance will begin with January 2020, consistent with the COVID-19 PHE determined to exist nationwide as of January 27, 2020, and will continue through the end of the PHE, which includes any subsequent renewals. This clarifies the applicability of the program's extreme and uncontrollable circumstances, which caused confusion in the March 31 rule. In the event the COVID-19 PHE extends through all of CY 2020, all shared losses for PY 2020 will be mitigated for all ACOs participating in a performance-based risk track.
- Due to the anticipated localized nature of COVID-19 infections and the unanticipated increase in expenditures, CMS is adjusting program calculations to mitigate the impact of COVID-19

on ACOs. CMS recognizes that the increased flexibilities implemented to allow healthcare providers to identify and treat COVID-19 patients will affect the level of Medicare Parts A and B expenditures during 2020. Specifically, CMS is concerned that the cost associated with treatment of acute care for COVID-19 will cause CY 2020 data to be a distorted reference year for payment estimates. In response, CMS is revising policies under the Shared Savings Program to exclude from Shared Savings Program calculations all Parts A and B fee-for-service (FFS) payment amounts for an episode of care for treatment of COVID-19, triggered by an inpatient service, and as specified on Parts A and B claims with dates of service during the episode. CMS will identify an episode of care triggered by an inpatient service for treatment of COVID-19 based on either (1) discharges for inpatient services eligible for the 20% diagnosis-related group (DRG) or (2) discharges for acute care inpatient services for treatment of COVID-19 from facilities that are not paid under the inpatient prospective payment system (IPPS) when the date of admission occurs within the COVID-19 PHE. CMS will define the episode of care as starting in the month in which the inpatient stay begins as identified by the admission date, all months during the inpatient stay, and the month following the end of the inpatient stay as indicated by the discharge date. In addition to excluding Parts A and B payment amounts with dates of service in the months associated with an episode of care for treatment of COVID-19, CMS will also exclude the affected months from total person years used in per capita expenditure calculations. CMS recognizes that the COVID-19 pandemic is an evolving situation and requests comment on the approach to adjusting program calculations to mitigate the financial impact of the pandemic on ACOs.

- CMS is expanding the definition of primary care services for purposes of determining beneficiary assignment to include telehealth codes for virtual check-ins, evisits, and telephonic communications. In response to the COVID-19 pandemic, CMS recognizes that there is an urgency to expand the use of technology to allow people who need routine care to remain in their homes, while maintaining access to the care they need. CMS provides a list of codes that will be defined as primary care services, including when they are furnished via telehealth during the PHE for the COVID-19 pandemic, beginning March 1, 2020.

M. Additional Flexibility for Resident Services Under the Teaching Physician Regulations

In its March 31 rule, CMS furnished flexibilities in regulations governing Part B PFS payment for teaching physicians and residents. The flexibility was extended further in the IFR. Generally, under Section 415.174, Medicare makes PFS payments in primary care settings for certain services of lower and midlevel complexity furnished by a resident without the physical presence of a teaching physician, referred to as the primary care exception, subject to certain conditions. In Section II.E of the March 31 rule (85 Fed. Reg. 19,245–19,246), CMS indicated that the physician presence requirement of a teaching physician can be met, at a minimum, through direct supervision by audio-video real-time communication technology. CMS also revised the scope of evaluation and management (E/M) codes that can be furnished under the primary care exception and amended Section 415.174 to allow all levels of office/outpatient E/M services furnished in primary care centers under the primary care exception to be furnished under direct supervision of the teaching physician by interactive telecommunication technology.

CMS made certain technical clarifications in the IFR to its rules to reflect the audio-video real-time requirement for communication technology. In addition, based on comments from the teaching hospital community, CMS clarified that a teaching physician may not only direct the care furnished by residents, but also review the services provided with the resident, during or immediately after the visit, remotely through virtual means via audio-video real-time communication technology. CMS also added services that fall within the primary care exception to further address the strain on resources caused by the COVID-19 crisis to incorporate additional telehealth E/M services, transitional care management, and communication technology–based services.

According to CMS, "taken together, these policies mean that, on an interim basis for the duration of the PHE for the COVID-19 pandemic, Medicare may make PFS payment for teaching physician services when

a resident furnishes a service included in this expanded list of services in primary care centers, including via telehealth, and the teaching physician can provide the necessary direction, management and review for the resident's services using audio-video real-time communications technology." This flexibility should provide added capacity for teaching hospitals during the PHE.

N. Payment for Audio-Only Telephone Evaluation and Management Services

As discussed in our White Paper on the March 31 rule, CMS expanded coverage for three time-based CPT codes—99441, 99442, and 99443—for telephone-only E/M services for use in situations where beneficiaries might not have access to, or chose not to use, interactive two-way audio-video technology required to that point to furnish Medicare telehealth services if offered by their practitioner.

CMS established separate payment for these audio-only telephone E/M services by finalizing work relative value units of 0.25, 0.50, and 0.75 respectively for each code, plus direct practice expense (PE) inputs consisting of three minutes of post-service registered nurse/licensed practical nurse/medical technical assistant clinical labor time. This was based on an assumption, possibly unrealistic under the circumstances, that although there are circumstances in which audio-only communication between practitioner and patient could be clinically appropriate, such encounters would not fully replace telehealth and in-person visits, particularly with respect to more complex care.

CMS reports in the IFR that since initially establishing these payment amounts, it heard from "stakeholders" that the use of audio-only services is more prevalent than CMS originally had anticipated. Rather than augmenting video-enabled telehealth services or face-to-face visits, the audio-only telephonic services are serving as a substitute for those encounters. As a result, CMS acknowledges that it did not accurately capture the intensity of furnishing an audio-only visit when it valued the services and set the payment amounts in the March 31 rule. As a result, CMS establishes in the IFR new relative value units and direct PE inputs for telephone E/M services based on analogous E/M codes for office/outpatient visits, specifically CPT codes 99212, 99213, and 99214. CMS reported in its April 30, 2020 press release that this revaluation will increase payments for these services from a range of about $14–$41 to about $46–$110. The payments are retroactive to March 1, 2020.

In addition, because CMS now recognizes that these audio-only services are being furnished as substitutes for telehealth and office/outpatient E/M services, the agency is adding them in the IFR to the list of Medicare telehealth services for the duration of the PHE. CMS also will be issuing a waiver for audio-only E/M services of the requirements that Medicare telehealth services must be furnished using video technology. Finally, CMS notes that beneficiaries still are liable for cost sharing associated with audio-only E/M services unless the practitioner has waived cost sharing pursuant to Office of the Inspector General's co-pay waiver guidance.

Notably, however, while many states have permitted audio-only communications for the duration of the crisis, not all have. CMS cannot alter state-based practice of medicine requirements, and unless a state specifically permits the performance of audio-only encounters, providers should not view CMS's flexibility here as carte blanche to perform these services without corresponding allowance by a state medical board. In addition, practitioners often face increased medical malpractice risk when performing services through audio-only methods. As such, unless a patient cannot participate in an audio-video encounter, practitioners should be wary of immediately defaulting to telephone-based visits.

O. Flexibility for Medicaid Laboratory Services

CMS is amending its regulations to allow for COVID-19 testing in non-office settings, as well as coverage for laboratory processing of self-collected COVID-19 tests that receive proper US Food and Drug Administration (FDA) authorization. This relaxation of policy will apply for not just the duration of the PHE, but also for any subsequent period of active surveillance. Further, CMS is giving states the ability to waive the requirement that there be a physician order as a precondition to coverage of the test.

P. Improving Care Planning for Medicaid Home Health Services

In continued recognition of the changing and diverse nature of skilled medical professionals, and to meet the urgent statutory directives of the CARES Act, CMS proposes for the Medicaid home health program similar changes made to the Medicare home health program for using nonphysician extenders, including NPs, CNSs, and PAs, for core aspects of home health services. The regulatory changes follow the March 31 rule, where the Medicaid home health regulations were amended to allow other licensed practitioners to order all components of home health services in accordance with state scope of practice laws for the period of the PHE. Now, these Medicaid changes are permanent and retroactive to March 1, 2020.

CMS notes that structural differences between the Medicare and Medicaid programs may not allow for perfect alignment. For example, Medicare allows a more extensive list of NPPs to order DME than the practitioners identified for Medicaid. To resolve this conflict, CMS will allow other licensed practitioners to order medical equipment, supplies, and appliances in addition to physicians, when practicing in accordance with state laws. The IFR amends the home health regulation at Section 440.70(a)(3) to apply the new list of practitioners as authorized practitioners who can order those services; specifically, part-time or intermittent nursing services, home health aide services, and, if included in the state's home health benefit, therapy services.

The IFR also removes the requirement that the NPPs described in Section 440.70(a)(2) have to communicate the clinical finding of the face-to-face encounter to the ordering physician. With expanding authority to order home health services, the CARES Act also provides that such practitioners are now capable of independently performing a face-to-face encounter for the patient for whom they are the ordering practitioner, in accordance with state law. If state law does not allow this new flexibility, the NPP is required to work in collaboration with a physician.

Q. Basic Health Program Blueprint Revisions

As of April 2020, Minnesota and New York are the only states operating a Basic Health Program (BHP), which is for specified individuals who do not qualify for Medicaid but whose income does not exceed 200% of the federal poverty level (FPL). As part of the BHP, the states are required to submit a BHP Blueprint to CMS for initial certification of the state's BHP and prior to making any significant changes to the certified BHP Blueprint. CMS will allow a state to submit a revised BHP Blueprint that makes temporary significant changes to respond to the COVID-19 PHE with the option for the state to make such changes effective retroactive to the start of the PHE.

R. Merit-based Incentive Payment System Qualified Clinical Data Registry Measure Approval Criteria

CMS is delaying for one year the implementation of Qualified Clinical Data Registry (QCDR) measure testing and collection of data on QCDR measures approved for the Merit-based Incentive Payment System (MIPS) program, now beginning with the 2022 performance year.

S. Application of Certain National Coverage Determination and Local Coverage Determination Requirements During the PHE

In the March 31 rule, CMS specified that national coverage determination and local coverage determination (LCD) clinical indications required for respiratory, home anticoagulation management and infusion pumps, and requirements for face-to-face or in-person encounters for evaluations, assessments, or certifications would not be enforced during the PHE. The IFR clarifies that physicians, practitioners, and suppliers must continue to document medical necessity for patient services in the patient medical record to ensure the medical record is sufficient to support payment for the services billed. CMS also will not enforce the clinical indications for therapeutic continuous glucose monitors in LCDs.

T. Delay in the Compliance Date of Certain Reporting Requirements Adopted for IRFs, LTCHs, HHAs, and SNFs

To accommodate updated patient assessment instruments, CMS has revised the compliance dates for certain Transfer of Health (TOH) information quality measures and certain Standardized Patient Assessment Data Elements (SPADEs) related to quality reporting for skilled nursing facilities (SNFs), HHAs, long-term care hospitals (LTCHs) and IRFs:

- SNF QRP data will now be due October 1 of the year that is at least two fiscal years after the end of the PHE.
- HHA QRP data will now be due January 1 of the year that is at least one full calendar year after the end of the PHE.
- LTCH QRP data will now be due October 1 of the year that is at least one full fiscal year after the end of the PHE.
- IRF QRP data will now be due October 1 of the year that is at least one full fiscal year after the end of the PHE.

CMS notes that the SNF QRP data compliance date is extended longer than for other providers to address related data concerns regarding the updated minimum data set.

CMS has consistently recognized that the PHE has impacted the public health system of data reporting that is important for a myriad of reasons, including quality performance ratings, payment methodologies and related data assessments, and reporting requirements. Through the IFR process, CMS has accommodated reporting deadlines for providers and health plans. Future rulemaking or guidance will be necessary to determine or finalize how these delayed data activities will take into account COVID-19 for future payments and assessments.

U. Update to the Hospital Value-Based Purchasing Program Extraordinary Circumstance Exception Policy

CMS recognizes the impact that unforeseen extraordinary circumstances, such as COVID-19, have on the ability of hospitals to perform under the Hospital Value-Based Purchasing (VBP) Program. CMS is updating the natural disaster/extraordinary circumstances exception (ECE) for Hospital VBP to include the ability for CMS to grant exceptions to hospitals located in entire regions or locales, which could include the entire United States, without a request where CMS determines that the extraordinary circumstance has affected the entire region or locale.

CMS will be able to grant ECE exceptions to hospitals that have not requested them where there is an extraordinary circumstance, such as the COVID-19 pandemic. This differs from the prior finalized policy where a hospital was required to submit a Hospital VBP Program ECE request form, including any available evidence of the impact of the extraordinary circumstance on the hospital's quality measure performance, within 90 calendar days of the date on which the natural disaster or other extraordinary circumstance occurred.

CMS will communicate its decision to grant an exception to all hospitals in a region or locale through routine communication channels to hospitals, vendors, and quality improvement organizations. For those hospitals in the region or locale that do not report the minimum number of cases or measures for a program year, the hospital will not receive a 2% reduction to its base operating DRG in the applicable program year, and will also not be eligible to receive any value-based incentive payments for the applicable program year.

CMS recognizes that discharge data during the COVID-19 PHE may not be fully reflective of their quality or cost of care and is granting an ECE for all hospitals participating in the Hospital VBP Program for the following reporting requirements:

- Hospitals will not be required to report National Healthcare Safety Network HAI measures and HCAHPS survey data for the following quarters: October 1, 2019–December 31, 2019 (Q4 2019), January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020). However, hospitals can optionally submit part or all of these data.
- CMS will exclude qualifying claims data from the mortality, complications, and Medicare spending per beneficiary measures for the following quarters: January 1, 2020–March 31, 2020 (Q1 2020) and April 1, 2020–June 30, 2020 (Q2 2020).

V. COVID-19 Serology Testing

CMS is covering FDA-authorized serology tests for beneficiaries with known current or known prior COVID-19 infections, or suspected current or suspected past COVID-19 infections.

W. Modification to Medicare Provider Enrollment Provision Concerning Certification of Home Health Services

Social Security Act Section 1866(j)(1)(A) requires that a process be established for enrolling providers and suppliers in the Medicare program. The overarching purpose of the enrollment process is to help ensure that providers and suppliers that seek to bill the Medicare program for services or items furnished to Medicare beneficiaries are qualified to do so under federal and state laws. The applicable provider enrollment regulations are largely, though not exclusively, contained in Part 424, subpart P (currently Sections 424.500 through 424.570).

The IFR amends the enrollment regulation to incorporate the physician extenders recognized for providing home health services by revising Section 424.507(b)(1) to include ordering/certifying physicians, PAs, NPs, and CNSs as individuals who can certify the need for home health services. This change to Section 424.507 is final and applicable to services provided on or after March 1, 2020.

X. Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges: Separate Billing and Segregation of Funds for Abortion Services

CMS is delaying implementation of the 2019 Program Integrity Rule, "Patient Protection and Affordable Care Act; Exchange Program Integrity" final rule (84 Fed. Reg. 71,674) that required separate billing for coverage of non-Hyde abortion services in light of the heightened burden qualified health plan (QHP) issuers are experiencing in response to the COVID-19 PHE. QHP issuers are required to collect two distinct premium payments for coverage of services, one for the coverage of non-Hyde abortion services, and one for coverage of all other services covered under a QHP. The prior extended deadline was set to be August 26, 2020; however, CMS acknowledges that the timeline for the COVID-19 PHE is uncertain, and there may be further delays past the 60-day extension.

Y. Requirement for Facilities to Report Nursing Home Resident and Staff Infections, Potential Infections, and Deaths Related to COVID-19

CMS codifies in a new Section 483.80(g)(1) agency guidance that requires nursing homes to report suspected and confirmed COVID-19 infections to the Centers for Disease Control and Prevention. The IFR also adds a provision at Section 483.80(g)(3) to require facilities to inform residents, their representatives, and families of those residing in facilities of confirmed or suspected COVID-19 cases in the facility among residents and staff. To that end, CMS recently issued a memorandum to State Survey Agency Directors updating requirements for notification of confirmed and suspected COVID-19 cases among residents and staff in nursing homes.

Z. Time Used for Level Selection for Office/Outpatient Evaluation and Management Services Furnished via Medicare Telehealth

CMS is revising its policy to specify that selection of the appropriate level of office/outpatient E/M code for services furnished via telehealth can be based on either medical decisionmaking (MDM) or time, with time including all of the time associated with E/M on the day of the encounter. The time to be used for leveling decisions were those typical times associated with office/outpatient E/M visits published on the CMS website.

The physician community brought to CMS's attention that the policy announced in the March 31 rule on typical times published on the CMS website does not match the typical times included in the office/outpatient E/M code descriptors used by the American Medical Association (AMA). In the IFR, CMS clarifies that the typical times used in the AMA code descriptors themselves are the appropriate times to be used for code selection. As such, providers should rely on those times when calculating the appropriate E/M level to bill.

AA. Updating the Medicare Telehealth List

Until now, CMS only has been able to add new services to the list of Medicare services that may be furnished via telehealth through notice and comment rulemaking. The IFR establishes that going forward, CMS will add new telehealth services on a subregulatory basis, possibly by just publishing new services to the web listing of telehealth services.

CMS notes that this will speed up the process of expanding services when it receives a request by practitioners to add, or identifies through its own internal review, a service that can be furnished in full by a distant site practitioner to a beneficiary in a manner that is similar to the in-person service. Any additional services added in this fashion will remain on the list only during the PHE—of course, if certain telehealth services act as a capable replacement for their in-person counterparts, we anticipate that CMS will likely permit expanded coverage of these services after the PHE ends.

BB. Payment for COVID-19 Specimen Collection to Physicians, Nonphysician Practitioners and Hospitals

Since the March 31 rule, CMS has further recognized the importance of expanding COVID-19 testing; specifically, the assessment of COVID-19 symptoms and exposure, and specimen collection for new patients. In an effort to expand the availability of testing, CMS is providing additional payment for assessment and COVID-19 specimen collection to support testing by hospital outpatient departments (HOPDs), physicians, and other practitioners.

CMS further acknowledges the inability to find a code that would specifically describe the services that would be furnished in the context of large-scale dedicated testing operations involving a physician or NPP. In response, for the duration of the PHE, CMS will recognize physician and NPP use of CPT code 99211 for all patients, not just patients with whom they have an established relationship, to bill for a COVID-19 symptom and exposure assessment and specimen collection provided by clinical staff incident to their services.

For HOPDs, CMS created a new E/M code solely to support COVID-19 testing for the PHE: HCPCS code C9803 (*Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (coronavirus disease [COVID-19]), any specimen source*). Cost sharing for this service will be waived when all other requirements under Section 6002(a) of the Families First Coronavirus Response Act are met.

CC. Payment for Remote Physiologic Monitoring Services Furnished During the PHE

CMS is establishing an interim policy for the duration of the COVID-19 PHE to allow remote physiologic monitoring (RPM) services to be reported to Medicare for periods of time that are fewer than 16 days or 30 days, but no less than 2 days, as long as the other requirements for billing the code are met. This is in response to stakeholder outreach that CPT coding guidance that the RPM service described by CPT code 99454 cannot be reported for monitoring of fewer than 16 days during a 30-day period.

Coronavirus COVID-19 Task Force

For our clients, we have formed a multidisciplinary **Coronavirus COVID-19 Task Force** to help guide you through the broad scope of legal issues brought on by this public health challenge. We also have launched a resource page to help keep you on top of developments as they unfold. If you would like to receive a daily digest of all new updates to the page, please subscribe now to receive our COVID-19 alerts.

Authors

GREGORY N. ETZEL
gregory.etzel@
morganlewis.com
+1.713.890.5755

KATHLEEN RUBINSTEIN
kathleen.rubinstein@
morganlewis.com
+1.713.890.5726

SUSAN FEIGIN HARRIS
susan.harris@
morganlewis.com
+1.713.890.5733

SUMMER SWALLOW
summer.swallow@
morganlewis.com
+1.713.890.5716

KATHLEEN MCDERMOTT
kathleen.mcdermott@
morganlewis.com
+1.202.739.5458
+1.617.341.7570

JACOB J. HARPER
jacob.harper@
morganlewis.com
+1.202.739.5260

SCOTT A. MEMMOTT
scott.memmott@
morganlewis.com
+1.202.739.5098

JONELLE C. SAUNDERS
jonelle.saunders@
morganlewis.com
+1.202.739.5828

ANDREW RUSKIN
andrew.ruskin@
morganlewis.com
+1.202.739.5960

Contacts

If you have any questions or would like more information on the issues discussed in this White Paper, please contact the authors or any of the following Morgan Lewis lawyers:

Washington, DC

Michele Buenafe	+1.202.739.6326	michele.buenafe@morganlewis.com
Kathleen McDermott	+1.202.739.5458	kathleen.mcdermott@morganlewis.com
Scott Memmott	+1.202.739.5098	scott.memmott@morganlewis.com
Andrew Ruskin	+1.202.739.5960	andrew.ruskin@morganlewis.com
Albert Shay	+1.202.739.5291	albert.shay@morganlewis.com
Howard Young	+1.202.739.5461	howard.young@morganlewis.com
Joyce Cowan, Consultant	+1.202.739.5373	joyce.cowan@morganlewis.com
Dani Elks	+1.202.739.5425	dani.elks@morganlewis.com
Jacob Harper	+1.202.739.5260	jacob.harper@morganlewis.com
Eric Knickrehm	+1.202.739.5859	eric.knickrehm@morganlewis.com
Ariel Landa-Seiersen	+1.202.739.5096	ariel.seiersen@morganlewis.com
Jonelle Saunders	+1.202.739.5828	jonelle.saunders@morganlewis.com

Houston

Donna Clark	+1.713.890.5767	donna.clark@morganlewis.com
Greg Etzel	+1.713.890.5755	gregory.etzel@morganlewis.com
Susan Feigin Harris	+1.713.890.5733	susan.harris@morganlewis.com
Scott McBride	+1.713.890.5744	scott.mcbride@morganlewis.com
Kathleen Rubenstein, Senior Health Policy Adviser	+1.713.890.5726	kathleen.rubinstein@morganlewis.com
Summer Swallow	+1.713.890.5716	summer.swallow@morganlewis.com
Banee Pachuca	+1.713.890.5715	banee.pachuca@morganlewis.com
Sydney Reed	+1.713.890.5105	sydney.reed@morganlewis.com

Philadelphia

Erin Rodgers Schmidt	+1.215.963.5163	margaret.rodgers-schmidt@morganlewis.com

San Francisco

Reece Hirsch	+1.415.442.1422	reece.hirsch@morganlewis.com

Los Angeles

Brian Jazaeri	+1.213.612.7333	brian.jazaeri@morganlewis.com

Boston

Mark Stein	+1.617.341.7757	mark.stein@morganlewis.com

Chicago

Lauren Groebe	+1.312.324.1478	lauren.groebe@morganlewis.com

About Us

Morgan Lewis is recognized for exceptional client service, legal innovation, and commitment to its communities. Our global depth reaches across North America, Asia, Europe, and the Middle East with the collaboration of more than 2,200 lawyers and specialists who provide elite legal services across industry sectors for multinational corporations to startups around the world. For more information about us, please visit www.morganlewis.com.