

Regulatory Considerations for a Post-PHE World

The COVID-19 federal public health emergency (PHE) declaration has been renewed eight times over the past two years since first being issued on January 31st, 2020. Currently set to expire on July 16th, 2022, industry opinion is split on how much longer the federal declaration will continue.

Throughout the pandemic, both the Centers for Medicare and Medicaid (CMS) and the department of Health and Human Services (HHS) have repeatedly committed to providing a 60-day notice before allowing the PHE to finally expire in order to wind down pandemic related policies and flexibilities. Since the deadline for providing a 60-day notice ahead of the current expiration date has passed as of May, it is anticipated that HHS will renew the PHE at least once more to push the declaration out until at least mid-October.

We suggest that healthcare providers start to consider what impact the end of the PHE will have on their practices in order to plan for a successful transition into a post-PHE landscape.

Regulatory Triggers

In an effort to alleviate burden and prioritize patient care, CMS has offered COVID-19 flexibilities within the Quality Payment Program (QPP) and for the Appropriate Use Criteria (AUC) mandate. As the PHE ends, providers should ensure plans are in place for compliance looking ahead to 2023.

Appropriate Use Criteria (AUC)

Often referred to as 'AUC' or 'Clinical Decision Support' (CDS), Medicare's Appropriate Use Criteria mandate requires ordering providers to consult a qualified clinical decision support mechanism when ordering advanced imaging studies for Medicare patients in outpatient settings. Ordering providers must provide the outcome of the consultation, in the form of modifiers and G-codes, to the furnishing provider to append to applicable claims in order for them to be paid once the program enters its 'penalty phase' (defined below).

Prior to the start of the PHE, the program has been in an operational testing period – meaning, the legal mandate is in place requiring ordering providers to perform this consultation but there is no impact on reimbursement if applicable claims are lacking the necessary AUC codes. During the 2022 rulemaking cycle, CMS tied the start of the 'penalty phase' to the end of the PHE.

Now the AUC penalty phase will begin **January 1st, 2023**, or the first year following the end of the COVID-19 public health emergency, whichever is the latter.

Providers would be well advised to take steps now to comply with the mandate and ensure operational flows are ready once the penalty phase begins. If your practice has yet to start preparing, waiting for an official end of the PHE (or 60 day notice) could severely limit the time left to make technical or educational updates making 2023 a risk for reimbursement.

Quality Payment Program

The QPP has offered several flexibilities, primarily applied by the organization automatically, since the 2019 performance year. The majority of flexibilities were granted under the Merit-based Incentive Payment Program (MIPs) track of the QPP, ultimately resulting in nearly zero penalties being imposed by the program for several years.

The QPP has chosen to offer an Extreme and Uncontrollable Circumstances (EUC) hardship application due to COVID since the 2020 performance year, allowing providers/groups/virtual groups/APM entities to request that any or all performance categories be reweighted to 0% of a final MIPS score. This hardship application effectively allows participants to opt-out of MIPS reporting without receiving a penalty if all performance categories are requested for reweighting. In addition to the allowing participants to apply for the hardship, CMS also applied reweighting policies automatically at the individual provider or category level which further lowered the number of penalties earned by participants.

However, the MIPs program has continued to ramp up in difficulty over the past few years and 2023 is primed to be the most challenging year yet due to scoring policy updates enacted for the 2022 performance year, combined with an anticipated penalty threshold of 85 points.

The QPP has opened COVID-19 EUC hardships for the 2022 performance year, but it is not expected that these will be available again in 2023.

Those that have 'opted out' of MIPS should be planful in terms of achieving performance goals next year, given that the program difficulty has increased since COVID flexibilities have been available.

If MIPS performance is a concern for your practice, steps can be taken now to help avoid or mitigate a penalty such as:

- Reviewing Quality measures applicable to the practice – consider alternative measures that can be added and understand which measures are 'topped out' and 'point capped'.
 - Topped out measures are measures with little variation in quality performance. Once a measure is 'topped out' participants will receive significantly fewer points for performance below 100%. Once a measure is 'point capped' the QPP will lower the maximum amount of points a measure is worth from 10 to 7 points. Many specialties are facing the challenge of earning a score above the penalty while reporting topped out/point capped measures.

- Reviewing Quality performance feedback (if available) – look for Quality measure performance below 100% and take steps to improve performance.
 - Depending on the Quality measure reported, you may discover an educational opportunity or template needing updated which will have a positive impact on performance.

Medicare/Medicaid Waivers

CMS has granted numerous waivers under the PHE that would be terminated either upon the end of the emergency period, 60 days after the waiver or modification was first published, or at the end of the year the PHE expires. These waivers are not required to remain in effect for the full duration of the PHE – for example, CMS opted to phase out many waivers related to [Skilled Nursing Facilities in April of this year](#). We suggest that practices evaluate which waivers, if any, have been utilized over the past 2 years and consider any operational changes needed after the waiver(s) are no longer available.

CMS has utilized their authority granted under Section 1135 of the Social Security Act to provide federal ‘blanket waivers’ within the following categories:

- Conditions of participation or other certification requirements
- Program participation and similar requirements
- Preapproval requirements
- Requirements that physicians and other health care professionals be licensed in the State in which they are providing services, so long as they have equivalent licensing in another State (this waiver is for purposes of Medicare, Medicaid, and CHIP reimbursement only – state law governs whether a non-Federal provider is authorized to provide services in the state without state licensure)
- Emergency Medical Treatment and Labor Act (EMTALA)
- Sanctions under the physician self-referral law (also known as the “Stark Law”)
- Performance deadlines and timetables may be adjusted (but not waived)
- Limitations on payment for health care items and services furnished to Medicare Advantage enrollees by non-network providers

Details on active waivers announced by CMS are available here:

<https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf>

Telehealth

Arguably, the most impactful and transformative healthcare waivers granted during the PHE relate to Telehealth. In order to facilitate patient care early on during the pandemic, CMS waived the majority of requirements that had, up until that point, limited telehealth availability to a very small population of beneficiaries. Once these geographical and technology requirements were gone, telehealth utilization skyrocketed which has prompted debate on making expansion permanent.

CMS did use its authority to permanently expand reimbursement for behavior health services conducted via telehealth in the 2022 Medicare Physician Fee Schedule. Certain aspects, such as geographical site requirements, require congressional intervention to modify and are outside of CMS's authority to permanently adopt within rulemaking.

While several bills offering permanent telehealth expansion have been introduced to Congress, these efforts seem to have stalled. However, Congress did include a provision within the Consolidated Appropriations Act of 2022 which will preserve telehealth flexibilities for 151 days after the official end of the PHE. Specifics include:

- The originating site of care will continue to include any site at which the patient is located, including the patient's home;
- Eligible practitioners to furnish telehealth services will include occupational therapists, physical therapists, speech-language pathologists and audiologists;
- Federally qualified health centers and rural health clinics can furnish telehealth services;
- Delaying the 6-month in-person requirement for mental health services furnished through telehealth until 152 days after the emergency. This includes the in-person requirements for federally qualified health centers and rural health clinics;
- Extending coverage and payment for audio-only telehealth services;
- Extending the ability to use telehealth services to meet the face-to-face recertification requirement for hospice care

For the majority of the PHE, reimbursement for telehealth services has been made in parity to in-person visits based on the expansion of the CMS telehealth list. We suggest that practices who have expanded, or started utilizing telehealth services, review the procedures and patients who will eventually be excluded from telehealth services upon the end of the PHE.

CMS's telehealth list is available for download here: <https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes>

Summary

While the exact end of the PHE is still uncertain, the resulting relaxed regulatory environment has persisted for an extended period of time - which will eventually end. Taking inventory of the impact that these flexibilities have on your practice will help outline needs for transitioning towards compliance once the declaration ends.

As always, ADVOCATE will keep you up to date on this and all issues impacting medical groups as they become available.

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