FEATURE

Postpandemic Regulatory Compliance

Recognize implications of PHE expired waivers and flexibilities

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During the Covid-19 pandemic, temporary federal regulatory waivers and flexibilities allowed healthcare providers to increase access to care and streamline the delivery of services. Now, many waivers and flexibilities will expire because they were intended to respond to critical needs during the pandemic, not to permanently replace standing rules. Ensure that your organization resumes compliance when waivers and flexibilities expire.

With the end of the Covid-19 public health emergency (PHE) on May 11, 2023, numerous federal regulatory waivers and flexibilities were terminated, greatly affecting patients, hospitals, health systems, physicians and other providers. Returning to normal requires organizations to roll back policies and practices that were in place for more than three years. This article addresses several of the expired waivers relating to the Medicare and Medicaid programs and identifies key areas for audit and remediation consideration.

Implications for hospitals

Hospitals and health systems are making significant operational changes as the healthcare regulatory environment returns to a prepandemic state. They are assessing existing procedures, policies and relationships that were shaped by the waivers and flexibilities granted under the PHE. During this process, they are realizing that managing the effect on operations and finances may prove challenging.

Medicaid continuous enrollment stops – One of the biggest ongoing changes is the end of Medicaid's continuous enrollment requirement, which prevented states from terminating an individual's Medicaid coverage. As a result of the change, a significant number of beneficiaries who gained coverage during the PHE now are at risk of losing it.

During 2024, states must complete a redetermination process that terminates coverage for any person who no longer qualifies for Medicaid or who fails to submit information required for such redetermination. Healthcare organizations in states that have not expanded Medicaid may see a higher number of individuals lose coverage compared to states that have expanded the program.

An increase in the number of uninsured patients will probably hurt hospital financial performance. Even if these individuals secure other coverage, a rise in bad debt may still occur, given the cost of required co-pays, premiums or high deductible health plans.

Operational waivers end – Another sizable challenge for hospitals and health systems of all sizes is the end of the operational waivers. Medicare has reverted to requiring a three-day inpatient stay before covering skilled nursing facility (SNF) care; the same is true for critical access hospital (CAH) swing beds.

To manage surges during the pandemic, the Centers for Medicare and Medicaid Services (CMS) waived certain requirements, such as location (e.g., rural area), size (25-bed limit) and average length of stay (96 hours) for CAHs. Additionally, hospitals can no longer place acute care patients in excluded distinct part unit beds (i.e., inpatient psychiatric or inpatient rehabilitation units) or place distinct part unit patients in acute care beds. A hospital also must now satisfy all eligibility requirements to maintain its status as a sole community or Medicare-dependent hospital.

Teaching hospital waivers stop – Teaching hospitals receiving graduate medical education payments from CMS also benefited from the Covid-19 waivers. Specifically, during

the PHE, a hospital's bed count for determining the indirect medical education (IME) calculation was based on what it was the day before the PHE was declared on January 31, 2020. A hospital, therefore, was not penalized if beds were temporarily added during the PHE, which could have reduced the IME payment.

If student medical residents of a teaching hospital were sent to other hospitals on an emergency basis as a result of the PHE and spent time training there, the originating hospital was able to claim the residents' time in its IME and direct graduate medical education (DGME) calculations. Further, if a resident performed duties at his/her home or at the patient's home during the PHE (that were within the scope of the approved residency program and that met the appropriate supervision requirements), the teaching hospital could consider that time for IME or DGME payment purposes. These benefits and others impacting teaching facilities ceased with the end of the PHE.

340B program flexibilities expire – Certain PHE flexibilities to the 340B drug pricing program have also expired with the end of the PHE, including:

- Exempting 340B site registration requirements on a case-by-case basis
- Allowing remote audits of covered entities
- Allowing some hospitals not normally qualified to buy drugs through a group purchasing organization (GPO) to purchase through a GPO if they could not get the 340B price or wholesale acquisition cost price

During the PHE, hospitals that were terminated from 340B because their Medicare disproportionate share adjustment fell below requirements were allowed to apply for readmission. That law has now expired.

Effects on physicians

The flexibilities and waivers under the PHE touched nearly every part of physicians' practices, from patients' ability to access care to the payment physicians receive. Now, physician practices must evaluate necessary changes as these policies unwind. While access to Covid-19 vaccinations and certain treatments generally will not be affected, a transition to a more traditional model of insurance coverage for vaccines and therapeutics will occur.

Vaccine payment rate reduction – CMS will discontinue higher Medicare payment rates for Covid-19 vaccinations at the end of 2023, and, starting January 1, 2024, the payment rate will align with the rate for other Medicare Part B preventive vaccines (approximately $30 per dose[1]). For practices with a higher number of traditional Medicare beneficiaries, this change could be beneficial.

Physician supervision requirements reestablished – During the PHE, services that were required to be directly supervised (e.g., the physician is physically present in the same suite of offices and immediately available to assist and direct) were allowed to be virtually supervised via real-time audio and video technology. In the 2024 Medicare Physician Fee Schedule Proposed Rule, CMS states it intends to extend this practice through the end of 2024 with the flexibility set to return to pre-PHE rules on January 1, 2025.

Substitute billing arrangements flexibility ended – Prior to the PHE, a physician could use a substitute physician (i.e., locum tenens) to provide services for no more than 60 continuous days, At the end of 60 days, he/she either needed to find another substitute or return to work for at least one day to reset the 60-day period.

The waiver allowed a physician to use a substitute for the entirety of the PHE and for an additional 60 continuous days upon expiration of the PHE.[2] The substitution flexibility enacted during the PHE has ended, and physicians must now return to pre-PHE rules for substitution coverage.

Telehealth flexibilities to end – Unlike many other flexibilities, most Medicare telehealth flexibilities originally implemented under the PHE will not be immediately affected. Congress authorized Medicare coverage and policies that have

[1] https://www.cms.gov/files/document/physicians-and-other-clinicians-cms-flexibilities-fight-covid-19.pdf, page 2
[2] Ibid, page 14.

facilitated access and payment for telehealth services, including audio-only services, to continue through December 31, 2024. Certain telehealth flexibilities, however, were discontinued at the end of the PHE, such as the use of telehealth in place of face-to-face visits required for some services.

Merit-based Incentive Payment System exemptions continue – CMS granted automatic exemptions to reporting requirements associated with the Merit-based Incentive Payment System (MIPS) for the 2020 and 2021 performance years. CMS required entities seeking an exemption due to Covid-19 to apply for the exemption using the Extreme and Uncontrollable Circumstances (EUC) application for 2022. For the 2023 performance year, CMS will continue to use the EUC application to allow providers to request reweighting of one or more MIPS performance categories due to the impact of Covid-19 on their practices (e.g., labor shortages).

Stark Law waivers

On March 30, 2020, CMS issued blanket waivers of sanctions under the physician self-referral law (i.e., Stark Law) to protect financial relationships and resulting referrals identified by CMS as pertaining to at least one Covid-19 purpose:

- Securing the services of healthcare professionals
- Ensuring the ability and capacity of healthcare providers to address patient and community need
- Addressing business interruption in order to maintain the availability of medical care for patients and the community
- Diagnosing or treating Covid-19
- Shifting the diagnosis/patient care to an appropriate alternative setting

The blanket waivers were given a retroactive effective date of March 1, 2020, and remained in place through May 11, 2023. The waivers outlined 19 different types of financial relationships including remuneration from an entity to a physician (or an immediate family member of a physician) that is above or below the fair market value (FMV) for services personally performed by the physician (or the immediate family member of the physician) to the entity.[3]

Many of the blanket waivers permitted compensation greater or less than FMV. Also, many waivers were bidirectional, meaning they addressed payment from an entity to a physician or the physician to the entity (as in the case of space, equipment, or purchased services). Several waivers permitted loans at less than FMV.

The blanket waivers did not require the submission of specific documentation or notice to CMS in advance of their use. Instead, CMS encouraged the development and maintenance of records in a timely manner and indicated that parties using the blanket waivers would be required to make records relating to their use available to CMS upon request.

Given the potential for post-PHE scrutiny and perhaps for years to come, a critical audit priority should be identifying and documenting any financial relationships that relied on the blanket waivers. Such relationships should also be terminated by the end of the PHE. Practically speaking, the more time that goes by, the more difficult it will become to document these items.

To begin the documentation process, hospitals and health systems should identify whether they entered into any financial relationships that relied on the blanket waivers. To assist the identification process, providers should consider the examples of the arrangements identified by CMS in its blanket waiver publication[4] and then stratify the arrangements for which blanket waivers were utilized based on risk level. For example, if your organization increased compensation to a physician during the PHE, ensure that documentation for the stated increase is complete and available upon request.

Many of the arrangements that used the blanket waivers had a stated business purpose of helping to cope with Covid-19 during the PHE. Consequently, the arrangements may also need to be evaluated from a commercial reasonableness perspective.

While FMV often deals with the amount of money to be exchanged between two parties, commercial reasonableness examines the business purpose of the arrangement. If the business purpose that was primarily related to Covid-19 has not been adjusted post-PHE, documentation should exist as to ongoing need.

Exhibit 1 summarizes key waivers and flexibilities, including areas that may need audit and remediation.

[3]https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf, page 8.
[4]Ibid, page 6.

Exhibit 1 – Summary of key waivers

Waiver and flexibility	Audit and remediation
1. Medicaid continuous enrollment provision	• Encourage Medicaid patients to respond to state requests for information relating to redetermination in a timely manner. • If coverage is terminated, assist patients in identifying alternative coverage or payment options.
2. SNF admission – Three-day prior hospitalization[5]	• Address policies and procedures for ensuring a Medicare beneficiary has a qualifying three-day prior hospitalization to qualify for SNF coverage.
3. Swing bed utilization[6]	• Address policies and procedures for ensuring a Medicare beneficiary has a qualifying three-day prior hospitalization to qualify for swing bed coverage.
4. Critical access hospitals[7]	• Discontinue use of more than 25 beds. • Adhere to 96-hour average length-of-stay requirements. • Discontinue use of any offsite nonrural locations.
5. Distinct part units[8]	• Ensure patients are treated in their dedicated units in order to receive payment for services.
6. Provider supervision[9]	• Identify any service requiring direct supervision and ensure that virtual supervision currently being used transitions back to direct supervision by January 1, 2025, in accordance with the 2024 Medicare Physician Fee Schedule proposed rule.
7. Teaching facilities	• Plan for any added beds to be considered in determining the hospital's IME payments.[10] • Discontinue claiming residents sent to other hospitals in IME and DGME full-time equivalent resident counts.[11] • Discontinue counting resident's time for activities at his/her home or a patient's home for purposes of Medicare IME or DGME payments.[12]
8. Telehealth exceptions[13]	• Discontinue use of telehealth for specific services no longer permitted under waivers.
9. Covid-19 vaccination payment[14]	• Assess the financial implication of a payment decrease starting in 2024.
10. Locum tenens billing arrangements[15]	• Comply with the requirement that locum tenens physicians provide services to Medicare patients over a continuous period of time no longer than 60 days.
11. Merit-based Incentive Payment System participation	• Evaluate need for EUC application and file for requested reweighting of one or more categories by January 2, 2024.[16] • Prepare to implement 2024 Quality Payment Program requirements.[17]
12. Stark Law waivers[18]	• Determine if a blanket waiver was used. • Stratify affected arrangements based on risk (e.g., low, medium, high). • Review documentation for affected arrangements to ensure appropriate support exists for reliance on the blanket waiver. • Consider the commercial reasonableness of the applicable arrangement.

[5] https://www.cms.gov/files/document/long-term-care-facilities-cms-flexibilities-fight-covid-19.pdf, page 5.
[6] https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf, page 12.
[7] Ibid, page 13.
[8] Ibid, page 14.
[9] Ibid, page 4.
[10] https://www.cms.gov/files/document/teaching-hospitals-physicians-medical-residents-cms-flexibilities-fight-covid-19.pdf, page 6.
[11] Ibid.
[12] Ibid, page 5.
[13] Ibid, page 4.
[14] https://www.cms.gov/files/document/hospitals-and-cahs-ascs-and-cmhcs-cms-flexibilities-fight-covid-19.pdf, page 2.
[15] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf, page 37.
[16] https://qpp.cms.gov/resources/covid19
[17] https://qpp.cms.gov/
[18] https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf

Resources

- PYA
  - End of the PHE Compliance Checklist
  - Stark Law Blanket Waiver Documentation Checklist
- Centers for Medicare and Medicaid Services - Frequently Asked Questions: CMS Waivers, Flexibilities, and the End of the COVID-19 Public Health Emergency

Conclusion

The provision of various waivers and flexibilities afforded significant relief to hospitals, health systems and physicians while they treated patients during the PHE. As your organization moves forward, review and transition practices and policies that were used from March 2020 to May 2023.

Many CMS flexibilities have expired, but healthcare providers should recognize that several flexibilities, including those related to telehealth, are extended for a period of time. Although extended, the flexibilities do have deadlines. Your providers should be aware of these and prepare for their future expiration. CMS provides various sources on its website to ensure compliance with the deadlines.

An audit of your organization's compliance with end-of-PHE requirements can identify overlooked items and facilitate remediation. Regular check-ups and any required adjustments should be part of your organization's ongoing practices. **NP**

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