Virtual Care Policy Update: What to Expect in Lame Duck

The Consolidated Appropriations Act (CAA), 2023 (Public Law 117-328), signed into law on December 29, 2022, extended certain key telehealth flexibilities instituted during the COVID-19 public health emergency (PHE) through **December 31, 2024.** These included the Medicare telehealth flexibilities, the telehealth safe harbor for health savings account (HSA)-eligible high deductible health plans (HDHPs), and the Acute Hospital Care at Home (AHCAH) Initiative. Without congressional action, these waivers and flexibilities will end on December 31, 2024.

Though the US Drug Enforcement Administration (DEA) issued a third temporary extension of its policy around the prescription of certain controlled substances through telemedicine, until December 31, 2025, further action from DEA is needed around a permanent policy.

This update provides information on these policies, relevant regulatory and congressional action, and the likelihood of further extensions before the end of this year.

BACKGROUND

Medicare Telehealth Flexibilities

Historically, the originating site and geographic requirements have stood as significant barriers to Medicare reimbursement of telehealth services. Before the COVID-19 PHE, Medicare generally reimbursed telehealth services provided to beneficiaries only when they were at a qualifying originating site (*e.g.*, practitioner office, hospital, rural health clinic) and were located in a rural area. Practically, this meant that beneficiaries were not permitted to receive telehealth services when they were located in their own homes. The originating site requirements are set forth in statute and may be modified only through congressional action.

In response to the COVID-19 pandemic, the US Department of Health and Human Services (HHS) used PHE authority and authority temporarily granted by Congress to provide waivers and flexibilities for telehealth services delivered to Medicare beneficiaries. As a result, during the PHE, more types of providers were able to deliver services via telehealth, and telehealth providers were able to receive Medicare reimbursement for a greater variety of virtual services and treat Medicare patients in more locations than ever before.

Because the flexibilities were originally tied to the duration of the PHE, Congress passed legislation to extend these flexibilities beyond the end of the PHE on May 11, 2023. Most recently, the CAA, 2023, extended these Medicare telehealth flexibilities until December 31, 2024:

- *Waivers to geographic and originating site restrictions.* As noted, before the pandemic, Medicare required that the patient be in a rural or certain health professional shortage area and use telehealth in an approved originating site, such as a hospital or physician office. Together, these restrictions limited beneficiaries' ability to access telehealth in more convenient locations, such as their home. Only about 2% of beneficiaries reside in ZIP codes that meet the traditional geographic and originating site criteria.

- *Expansions of qualifying providers.* This provision allows commonly accessed providers such as physical therapists, occupational therapists, and speech language pathologists to bill for telehealth services. If this flexibility were to expire, CMS would have to revert to

policies that restrict the types of providers that can deliver reimbursable care virtually to Medicare beneficiaries.

- *FQHCs and RHCs.* This flexibility allows federally qualified health centers (FQHCs) and rural health clinics (RHCs) to serve as distant site telehealth providers. In 2023, FQHCs made up the greatest share of telehealth Medicare fee-for-service (FFS) visits. Expiration of this flexibility would prevent low-income and geographically isolated individuals from utilizing telehealth visits to maintain continuity of care with their existing provider or connect with clinicians best equipped to meet their needs.

- *Audio-only communications.* Allowing telehealth to be provided through audio-only communications is particularly relevant in rural communities, where unavailable or unreliable broadband access could preclude patients from accessing telehealth through other means.

- *Flexibility in hospice care face-to-face requirement.* Allowing telehealth to be used for a required face-to-face encounter prior to the recertification of a patient's eligibility for hospice care aims to ensure continuity of care, particularly in isolated rural and underserved communities.

- *Waiver to mental health services in-person requirement.* Waiving the in-person requirement for telehealth treatment of certain mental health conditions expanded mental and behavioral healthcare access for Medicare beneficiaries. In 2022, 50% of FFS Medicare common psychotherapy claims were delivered via telehealth. With this flexibility, whether a patient requires an in-person visit prior to commencing mental telehealth treatment is left to the healthcare provider's clinical judgment.

HSA-HDHP Telehealth Safe Harbor

Through Section 3701 of the CARES Act (2020), Congress created a safe harbor allowing those with HSA-eligible HDHPs to have telehealth services covered on a first-dollar basis. The CAA, 2022, extended this safe harbor from April 1, 2022, through December 31, 2022. (There was a gap in coverage from January 1, 2022, to March 31, 2022.) The CAA, 2023, extended the safe harbor again from January 1, 2022, through December 31, 2024.

This flexibility was never tied to the existence or duration of the COVID-19 PHE. As a result, unlike the Medicare telehealth flexibilities, Congress needed to repeatedly step in to extend this policy since its original enactment in 2020.

Acute Hospital Care at Home Initiative

In the midst of the COVID-19 PHE, the Centers for Medicare & Medicaid Services (CMS), using its PHE flexibilities, issued waivers to certain Medicare hospital conditions of participation (CoPs) and that, along with the PHE-related telehealth flexibilities, allowed Medicare-certified hospitals to furnish inpatient-level care in patients' homes. Addressing hospital bed capacity during the pandemic was a high priority for CMS. These waivers and flexibilities, collectively referred to as the AHCAH Initiative, included:

- Waiver of the CoP requiring nursing services to be provided on-premises 24 hours a day, seven days a week.

- Waiver of the CoP requiring immediate on-premises availability of a registered nurse for care of any patient.

- Waiver of CoPs that define structural and physical environment criteria specific to the hospital setting.

- Telehealth flexibility allowing the home or temporary residence of an individual to serve as an originating telehealth site.

- Telehealth flexibility allowing a hospital to use remote clinician services in combination with in-home nursing services to provide inpatient-level care in the patient's home.

Under the AHCAH Initiative, hospitals must also comply with existing state licensure requirements.

As with the Medicare telehealth flexibilities, in the CAA, 2023, Congress extended the AHCAH Initiative until December 31, 2024.

When reviewing AHCAH waiver requests, CMS divides hospitals into two groups based on their experience delivering hospital-level care at home. Expedited waivers are available for experienced programs that have treated at least 25 patients meeting inpatient admission criteria, and detailed waivers are available for all other hospitals. CMS reviews waiver requests to assess the hospital's ability to meet waiver requirements, provide specific services, and maintain appropriate safeguards. CMS also interviews hospitals requesting a waiver under the AHCAH Initiative to discuss the operations of the hospital's program and the hospital policies that will enable it to fulfil waiver requirements.

Hospitals that furnish inpatient-level care under AHCAH are paid the same Inpatient Prospective Payment System rates that they would be paid if the patient was treated at the hospital facility.

DEA Regulation of Prescription of Certain Controlled Substances via Telemedicine

The Ryan Haight Online Pharmacy Consumer Protection Act of 2008 requires a telemedicine provider to perform an in-person medical evaluation of a patient prior to prescribing a controlled substance to that patient, unless an exception applies. The law lays out seven exceptions:

1. The patient is being treated in and is physically located in a hospital or clinic.
2. The patient is being treated by and in the physical presence of another practitioner.
3. The patient is being treated by a provider employed by the Indian Health Services.
4. The treatment is occurring during a PHE declared by the HHS Secretary involving locations and controlled substances designated by the Secretary and the US Attorney General.
5. The patient is being treated by a practitioner who holds a special registration.
6. There is a medical emergency and the patient is being treated by an employee of the Veterans Health Administration (provided that certain additional requirements are met).
7. The patient is being treated under other circumstances that the HHS Secretary and the US Attorney General have jointly, by regulation, determined to be consistent with effective controls against diversion and otherwise consistent with the public health and safety.

The controlled substance prescribing flexibilities invoked in January 2020 in response to the COVID-19 PHE (exception 4 above) were set to end with the termination of the PHE on May 11, 2023. However, DEA regulation put in place temporary extensions that kept the PHE policies in place through December 31, 2024. In November 2024, DEA finalized a further extension of the flexibilities for an additional year, through December 31, 2025.

RELEVANT REGULATORY ACTION

CMS Regulation of Medicare Telehealth Flexibilities

CMS uses the annual Medicare Physician Fee Schedule (PFS) rulemaking to address telehealth coverage and reimbursement policies. CMS is required by statute to finalize certain Medicare annual payment rules, including the final PFS rule, 60 days before the end of the calendar year. CMS released the CY 2025 PFS on November 1, 2024. Because Congress had not passed any extension of telehealth flexibilities at the time of the final PFS rule, CMS had to assume that most telehealth flexibilities would end for CY 2025. CMS stated that this assumption limited its ability to extend coverage and reimbursement for telehealth services. CMS noted in the final PFS rule that, absent congressional action, the rules around telehealth will revert to the statutory limitations that were in place prior to the pandemic, including the restrictions on geography, site of service, and practitioner type.

DEA Regulation of Prescription of Certain Controlled Substances via Telemedicine

February 2023: On February 24, 2023, the DEA issued two proposed rules (the Telemedicine Controlled Substance Proposed Rule and the Telemedicine Buprenorphine Proposed Rule) to establish additional potential pathways for the prescription of certain controlled substances in limited quantities via telehealth without an initial in-person medical examination. The key highlights of these proposed rules were as follows:

- Telehealth providers would no longer be able to prescribe Schedule II controlled substances or narcotics without an in-person evaluation.
- Telehealth providers would be able to prescribe a 30-day supply of Schedule III – V controlled substances or buprenorphine as medication for opioid use disorder without an in-person evaluation, but an in-person evaluation would be required for any renewal of such prescriptions.
- An exception for provider-patient relationships formed via telehealth during the COVID-19 PHE would allow telehealth providers to continue prescribing Schedule II – V controlled medications through November 7, 2023. After that, an in-person evaluation would be required to continue prescribing.
- An in-person evaluation could be conducted by the prescribing telehealth provider, by another DEA-registered provider who participated in a real-time audio-visual telehealth consultation with the patient and the prescribing provider, or by another DEA-registered provider who had performed an in-person evaluation of the patient and referred the patient to the prescribing provider.
- The need for an in-person evaluation would make it more challenging for patients who face significant barriers to accessing care without telehealth to continue receiving the controlled medications they need.

Notably absent from the proposed rules was a “special registration” process. Under the Ryan Haight Act, a prior in-person medical evaluation is not required if the practitioner holds a special registration (exception 7). However, in the 14 years since the act’s passage, the DEA has failed to establish the special registration process for qualified providers (even though Congress imposed a deadline of October 2019 in the 2018 SUPPORT for Patients and Communities Act for the promulgation of final regulations for the special registration process). In the proposed rules, the DEA opted not to implement the special registration process and instead invoked its authority under a different provision of the Ryan Haight Act.

The DEA received a record 38,000 comments in response to the proposed telemedicine rules, including comments from federal lawmakers. Many stakeholders pointed out that the requirement for an in-person evaluation would make it more challenging for patients who face significant barriers to accessing care without telemedicine to continue receiving the controlled medications they need.

May 2023: The DEA issued the May 2023 temporary rule, extending telemedicine flexibilities adopted during the PHE through November 11, 2023, for new patients, and November 11, 2024, for patients established on or before November 11, 2023. The agency indicated that it would further evaluate its proposed telemedicine rules in light of stakeholders' comments.

October 2023: On October 6, 2023, the DEA issued a temporary rule extending the full set of telemedicine flexibilities adopted during the PHE through December 31, 2024. This extension authorizes all DEA-registered practitioners to prescribe Schedule II – V controlled medications via telemedicine through December 31, 2024, regardless of when the practitioner-patient relationship was established.

June 2024: A proposed rule arrived at the Office of Management and Budget (OMB) for review on June 13, 2024. Once OMB clears the proposed rule, DEA can release it at any time. While the text of the proposed rule is not yet public, the rule's title, "Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation," suggests it is DEA's updated proposal. Of note, regulations do not often remain at OMB for longer than 90 days unless agencies are still engaged in review and potential policy changes. This suggests that there has been significant feedback that DEA still working through.

November 2024: On November 15, 2024, the DEA issued a third temporary rule extending the telemedicine flexibilities adopted during the PHE for an additional year, through December 31, 2025. In the rule, DEA states that this additional time will allow it (and also HHS, for rules that must be issued jointly) to promulgate proposed and final regulations that are consistent with public health and safety, and that also effectively mitigate the risk of possible diversion. Read our +*Insight* for a full breakdown of the extension.

RELEVANT CONGRESSIONAL ACTION

Medicare Telehealth Flexibilities

The US House of Representatives Ways and Means Committee considered and passed the Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261), a two-year extension of all the Medicare telehealth flexibilities, in May 2024. The House Energy and Commerce Committee passed a similar bill, the Telehealth Modernization Act of 2024 (H.R. 7623), in September 2024. Both bills received unanimous support, and both include provisions that would offset the reported $4 billion in expenditures for the two-year extension. Both bills still need to be considered on the floor of the House. The US Senate has yet to take up a specific piece of legislation on an extension.

HSA-HDHP Telehealth Safe Harbor

The Telehealth Expansion Act of 2023 (H.R. 1843/S. 1001) would provide for a permanent change in services allowed pre-deductible for HSA-eligible HDHPs to include telehealth and remote care services. This policy would essentially make the pandemic-era flexibility permanent. H.R. 1843 passed out of the House Ways and Means Committee in June 2023 with a vote of 30 yeas and 12 nays. It still awaits floor consideration. The Senate has taken no action on S. 1001. The bill sponsors continue to negotiate with committee, House, and Senate leadership on next steps.

Acute Hospital Care at Home Initiative

The CAA, 2023, effectively decoupled the AHCAH from the expiration of the COVID-19 PHE by extending the waiver through December 31, 2024. The CAA, 2023, also directed the Secretary to evaluate several aspects of the AHCAH Initiative, including:

- The criteria established by participating hospitals to determine which individuals qualify for AHCAH services.
- Socioeconomic information on beneficiaries treated under AHCAH.
- The clinical conditions treated and diagnosis-related groups associated with discharges from the inpatient setting versus under AHCAH.
- The quality of care furnished to individuals treated in the inpatient setting versus individuals with similar conditions and characteristics treated through AHCAH.
- Patients' experience with care under AHCAH.
- The costs incurred by furnishing care in the inpatient setting versus through AHCAH.
- The quantity, mix, and intensity of services furnished through inpatient care, versus AHCAH.

In September 2024, CMS issued a report studying these aspects of the AHCAH Initiative.

The Preserving Telehealth, Hospital, and Ambulance Access Act (H.R. 8261) and the Telehealth Modernization Act of 2024 (H.R. 7623), mentioned above, both propose a five-year extension of the initiative. The Senate has not considered a specific piece of legislation to extend the AHCAH Initiative but reportedly supports extension.

DEA Regulation of Prescription of Certain Controlled Substances via Telemedicine

Lawmakers have been following this issue closely. In September 2023, a bipartisan group of senators wrote to the DEA, expressing concerns with the February 2023 proposed rules and imploring the DEA to create a special registration process. They cited the SUPPORT Act's requirement and noted that the goal of the special registration is to allow medical evaluations via telehealth more broadly, which the senators stated the proposed rule would not accomplish.

On August 29, 2024, a senator issued a statement expressing further concern about the policies that may be included in the June 2024proposed rule.

On October 15, 2024, two additional congressional letters to DEA were released. The first was a bipartisan letter led by Senators Sheldon Whitehouse (D-RI), Lisa Murkowski (R-AK), Mark Warner (D-VA), and Marsha Blackburn (R-TN) and signed by seven other senators. The second was a bipartisan letter led by Representatives Doris Matsui (D-CA) and Buddy Carter (R-GA) and signed by 16 other Members. Both letters urged the DEA to extend the current flexibilities.

NEXT STEPS AND TIMING CONSIDERATIONS

Congress will need to address the extension of the Medicare telehealth flexibilities, telehealth safe harbor for HSA-eligible HDHPs, and the AHCAH Initiative during the lame duck. The uncertainty about when Congress will act, and how long the extensions will be, is creating many questions and causing confusion for patients and providers.

If Congress passes an extension of the **Medicare telehealth flexibilities** in the lame duck session, CMS will have to determine how to address any updates and changes quickly. CMS could issue a separate interim final rule that updates or creates new telehealth policies, but depending on when the legislation passes, that may be difficult to accomplish before January 1, 2025. If Congress does not act before the PFS final rule goes into effect on January 1, 2025, the policies in that final rule will become effective without accounting for any potential continuation of the flexibilities.

For the **HSA-eligible HDHP telehealth safe harbor**, a permanent policy such as that contemplated in H.R. 1843/S. 1001 will not pass this year. However, some stakeholders, including bill

sponsors, are advocating for a short-term extension to be included in any end-of-year legislative package. Supporters of the policy are concerned that increasing out-of-pocket costs for individuals with HDHPs may negatively impact patient access to telehealth and remote care services, especially specialty care. Some stakeholders have also noted that waiting until the end of the year to address the extension may create uncertainty for patients, providers, and health plans. Other commenters have expressed concerns that HDHPs are not robust, comprehensive plans, and have argued that moving services pre-deductible does not solve for a high deductible.

Congress appears poised to extend **AHCAH** beyond 2024 in an end-of-year legislative package. The expectation among lawmakers is that the Congressional Budget Office will again score AHCAH extension as having negligible budgetary effects (as it did when the CAA, 2023, initially extended AHCAH), making inclusion of an extension likely in end-of-year legislation.

The **final DEA rule temporarily extending the current flexibilities for the prescription of controlled substances via telemedicine** is welcome news to most stakeholders. It will likely provide some certainty for patients and providers while DEA continues to consider a permanent policy. Policymakers are engaged on this issue and interested in ensuring that DEA proposes a solution that carries out the original intent of Ryan Haight while accounting for the innovation and technology that has emerged since the law was originally passed.

Any policy consideration of these and other policies during the lame duck session of Congress may be impacted by several factors:

- *The outcome of the election.* Given that Republicans will hold both chambers in the 119th Congress, they may prefer to defer deliberation on policies that could otherwise have been negotiated as part of an end-of-year legislative package.
- *Whether there is a federal-funding-driven end-of-year legislative package.* If there is no broader healthcare-focused legislative package, a small package of extenders will be necessary to address several bipartisan health policies set to end on December 31, 2024. Expiring policies include the above Medicare telehealth flexibilities, community health center funding, the National Health Service Corps, and many others.
- *The available offsets.* While the estimated cost of a short-term extension of the HDHP safe harbor is not significant, finding bipartisan offsets in the health policy space is a constant uphill battle.

Lame duck will be a busy time, with a primary focus on funding the government and addressing expiring policies such as those mentioned in this update. Stakeholders should continue to engage with policymakers on their virtual care policy priorities to ensure inclusion in any end-of-year legislative package.

For more information, please contact Rachel Stauffer or Leigh Feldman.