**COVID-19 & Digital Health**

*Key Policy Actions & Guidance re COVID-19 – What We Have*

***NEW* CMS GENERAL PROVIDER TELEHEALTH AND TELEMEDICINE TOOL KIT** <https://www.cms.gov/files/document/general-telemedicine-toolkit.pdf>

***NEW* CMS ESRD PROVIDER TELEHEALTH AND TELEMEDICINE TOOL KIT** <https://www.cms.gov/files/document/esrd-provider-telehealth-telemedicine-toolkit.pdf>

**EXPANSION OF TELEHEALTH WITH 1135 WAIVER** (Medicare Telehealth Services)

* For the duration of the COVID-19 Public Health Emergency, Medicare will make payment for Medicare telehealth services furnished to patients in broader circumstances.
* Starting March 6, 2020 and for the duration of the COVID-19 Public Health Emergency, Medicare will make payment for professional services furnished to beneficiaries in all areas of the country in all settings (not just HPSAs).
* Medicare will make payment for Medicare telehealth services furnished to beneficiaries in any healthcare facility and in their home for the duration of the COVID-19 Public Health Emergency.
* The Medicare coinsurance and deductible would generally apply to these services; however, HHS OIG is providing flexibility for healthcare providers to reduce or waive cost-sharing for telehealth visits paid by federal healthcare programs.
* HHS will not conduct audits to ensure that such a prior relationship existed for claims submitted during this public health emergency.
* CMS Announcement: <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>
* CMS FAQ: <https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

**VIRTUAL CHECK-INS** (HCPCS code G2012 and HCPCS code G2010)

* Virtual check-in services can only be reported when the billing practice has an established relationship with the patient.
* Not limited to only rural settings or certain locations.
* Individual services need to be agreed to by the patient; however, practitioners may educate beneficiaries on the availability of the service prior to patient agreement.
* Virtual check-ins can be conducted with a broader range of communication methods, unlike Medicare telehealth visits, which require audio and visual capabilities for real-time communication.
* CMS Announcement: <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>
* CMS FAQ: <https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

**E-VISITS** (CPT codes 99421-99423 and HCPCS codes G2061-G206)

* Patients communicate with their doctors without going to the doctor’s office by using online patient portals.
* These services can only be reported when the billing practice has an established relationship with the patient.
* No geographic or location restrictions for these visits.
* Individual services need to be initiated by the patient; however, practitioners may educate beneficiaries on the availability of the service prior to patient initiation.
* Medicare coinsurance and deductible would generally apply to these services.
* CMS Announcement: <https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet>
* CMS FAQ: <https://edit.cms.gov/files/document/medicare-telehealth-frequently-asked-questions-faqs-31720.pdf>

**MEDICARE ADVANTAGE ORGANIZTIONS AND PARD D SPONSORS**

* CMS has issued information to Medicare Advantage Organizations and Part D Sponsors to inform them of the obligations and permissible flexibilities related to disasters and emergencies resulting from COVID-19.
* Link: <https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf>

**PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS**

* In guidance to PACE Organizations (POs), CMS recognizes that there may be circumstances where a PO needs to implement strategies that do not fully comply with programmatic requirements in order to protect beneficiaries from the spread of the virus. The agency will take those situations into consideration when conducting monitoring or oversight activities of POs. This will allow POs to use strategies including, for example, using telehealth to provide patient assessments that would normally be conducted on an in-person basis or limiting PACE center attendance in order to minimize the potential for exposure.
* Link: <https://www.cms.gov/newsroom/press-releases/cms-sends-guidance-programs-all-inclusive-care-elderly-pace-organizations>

**QUALITY PAYMENT PROGRAM**

* CMS has announced it is granting exceptions from reporting requirements and extensions for clinicians and providers participating in Medicare quality reporting programs with respect to upcoming measure reporting and data submission for those programs. The action comes as part of the Trump Administration’s response to 2019 Novel Coronavirus (COVID-19).
* Link: https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting

**MEDICAID & CHIP**

* CMS has released new tools to support state Medicaid and Children’s Health Insurance Programs (CHIP) during the 2019 Novel Coronavirus (COVID-19) outbreak:
  + 1115 Waiver Opportunity and Application Checklist: <https://www.medicaid.gov/medicaid/section-1115-demonstrations/1115-application-process/index.html>
  + 1135 Waiver Checklist: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/cms-1135-waivers/index.html>
  + 1915(c) Appendix K Template: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/hcbs/appendix-k/index.html>
  + Medicaid Disaster State Plan Amendment Template: <https://www.medicaid.gov/state-resource-center/disaster-response-toolkit/state-plan-flexibilities/index.html>

**HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)**

* Effective immediately, the HHS Office for Civil Rights (OCR) will exercise enforcement discretion and waive penalties for HIPAA violations against health care providers that serve patients in good faith through everyday communications technologies, such as FaceTime or Skype, during the COVID-19 nationwide public health emergency.
* OCR Announcement: <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html>; <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf>

**PRESCRIBING OF CONTROLLED SUBSTANCES**

* For as long as the Secretary’s designation of a public health emergency remains in effect, DEA-registered practitioners may issue prescriptions for controlled substances to patients for whom they have not conducted an in-person medical evaluation, provided all of the following conditions are met:
  + The prescription is issued for a legitimate medical purpose by a practitioner acting in the usual course of his/her professional practice
  + The telemedicine communication is conducted using an audio-visual, real-time, two-way interactive communication system.
  + The practitioner is acting in accordance with applicable Federal and State law.
* If the prescribing practitioner has previously conducted an in-person medical evaluation of the patient, the practitioner may issue a prescription for a controlled substance after having communicated with the patient via telemedicine, or any other means, regardless of whether a public health emergency has been declared by the Secretary of Health and Human Services, so long as the prescription is issued for a legitimate medical purpose and the practitioner is acting in the usual course of his/her professional practice. In addition, for the prescription to be valid, the practitioner must comply with any applicable State laws.
* Announcement: <https://deadiversion.usdoj.gov/coronavirus.html?inf_contact_key=e475ad72cf428bcacdb0e59dbb26b0eb680f8914173f9191b1c0223e68310bb1>

**FDA REGULATION OF NON-INVASIVE RPM MEDICAL DEVICES**

* The FDA has issued guidance to provide a policy to help expand the availability and capability of non-invasive remote monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act.
* Link: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during>

**BROADBAND CONNECTIVITY**

* FCC Chairman Ajit Pai recruited numerous broadband service providers to sign the Keep Americans Connected Pledge, which reads as follows:

“Given the coronavirus pandemic and its impact on American society, [[Company Name]] pledges for the next 60 days to:

(1) not terminate service to any residential or small business customers because of their inability to pay their bills due to the disruptions caused by the coronavirus pandemic;

(2) waive any late fees that any residential or small business customers incur because of their economic circumstances related to the coronavirus pandemic; and

(3) open its Wi-Fi hotspots to any American who needs them.”

Link: <https://docs.fcc.gov/public/attachments/DOC-363033A1.pdf>

* FCC has waived, until September 30th, 2020, gift rules for the Rural Healthcare Fund and E-Rate Program to allow providers to upgrade recipients’ network capacity, and provide Wi-Fi hotspots to schools and libraries to administer to students who don’t have access to the internet at home.  
  Link: <https://www.fcc.gov/document/fcc-acts-support-telehealth-remote-learning-during-coronavirus>
* FCC waiving various spectrum use requirements on communications service providers (e.g., <https://www.fcc.gov/document/fcc-grants-verizon-temporary-spectrum-access-during-covid-19-pandemic>)

*What We Still Need*

* Clarity that RPM codes 99453, 99454, 99457, and 99458 can be used to address COVID-19 and other acute illnesses (as opposed to chronic care per PFS final rule)
* HHS OIG to enable the provisioning of RPM tools (and other connected health tech) under the Anti-Kickback Statute [or take the carveout approach from C4H Act 2.0] for COVID-19
* OIG waiver of copays for RPM or OIG flexibility for other digital health modalities (RPM, virtual visits) similar to stated approach for Medicare Telehealth Services
* CMS enforcement discretion and not require a prior relationship with the physician before furnishing Medicare telehealth services or RPM during the COVID-19 public health emergency
* Direct the Secretary of HHS to allow CMS enforcement discretion to eliminate face-to-face requirements for any digital health (telehealth or RPM, and home INR monitoring services [HCPCS G0248 and G0249]) service in order to establish a proper physician/patient relationship
* Medicare beneficiaries should be able to access respiratory therapy services necessary for their recovery via telehealth and remote monitoring solutions.
* HHS should pay for Medicare telehealth services furnished by FQHCs and RHCs.
* Prior authorization (PA):
  + Waiver for all CMS programs (FFS, MA, Part D) for all vulnerable patients (by way of age or disability) who are more susceptible to COVID-19.
  + No PAfor COVID-19 testing and COVID-19-related therapies and treatments.
  + Encourage commercial insurers, like CMS, to waive all PA requirements.
* HIPAA:
  + OCR guidance clarifying that encrypted communications services that store non-sensitive PHI for limited periods are conduits.
  + Direct HHS Office for Civil Rights (OCR) to exercise enforcement discretion and waiving penalties for HIPAA violations re RPM.
  + Support relaxation of state law/regulations that impede the use of non-HIPAA compliant platforms for telehealth communications.
* CMS to modify the MA/Part D risk adjustment policy to incorporate diagnoses from telehealth encounters (currently telehealth is not “risk adjustable” as it is not a “face-to-face” visit).
* Licensure
  + State-level action to address state licensure challenges for interstate use of digital modalities.
  + State-level action to permit further clinicians (retired physicians, medical students, etc.) to treat COVID-19 patients.
* IDTFs should be permitted to bill the 99453 and 99454 RPM codes (despite unofficial guidance from CMS that they can, MACs are not allowing IDTFs to bill these codes currently).
* Broadband availability efforts by FCC:
  + New authority and allocations to support connected health
  + TV White Spaces deployed nationally in underserved and unserved areas
* Enable AI tools through:
  + Emergency HCPCS code(s) support for “narrow” AI use cases (e.g., triaging chatbots?)
  + Grants for coronavirus spread predictions/testing needs
  + Streamlined pathway to FDA approval for critical AI uses in addressing COVID-19

*Resources*

Licensure:

* ATA: <https://www.americantelemed.org/press-releases/ata-calls-on-governors-to-recognize-out-of-state-licensed-clinicians-and-waive-telemedicine-restrictions-to-help-combat-covid-19/>; <https://cdn2.hubspot.net/hubfs/5096139/Files/Policy%20Docs_letters,%20RFI,%20etc./ATA%20COVID-19%20One%20Pager%20Waiving%20State%20Licensing%20Restrictions%20FINAL.pdf>
* FSMB: <https://www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declarations-licensure-requirement-covid-19.pdf>
* NCSBN: <https://www.ncsbn.org/State_COVID-19_Response.pdf>
* Wheel: https://www.wheel.com/blog/up-to-date-emergency-licensing-for-clinicians-1/

Stakeholder Guidance:

* ACC: <http://connectwithcare.org/telehealth-guidance-documents-during-the-covid-19-pandemic/>
* AMA: [https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice](https://www.ama-assn.org/practice-management/digital/ama-quick-guide-telemedicine-practice?utm_source=twitter&utm_medium=social_ama&utm_term=3207044834&utm_campaign=Public+Health)
* ATA: <https://info.americantelemed.org/covid-19-news-resources>
* MSNVA: <https://msnva.org/marketplace-doctorstelemed>; <https://msnva.org/telehealth-regs>
* NAHRC: <https://www.web.narhc.org/News/28256/NARHC-Sends-Letter-to-Congress-on-Teleheath-Issues>
* Nixon Law Group: <https://www.nixonlawgroup.com/covid-19-telehealth-and-rpm-resources>
* Powers Law Group: <https://www.powerslaw.com/news-events/>
* CCHP: <https://www.cchpca.org/resources/covid-19-telehealth-coverage-policies>;  <https://www.cchpca.org/sites/default/files/2020-03/CORONAVIRUS%20TELEHEALTH%20POLICY%20FACT%20SHEET%20MAR%2016%202020%203%20PM%20FINAL.pdf>
* HIMSS: [www.HIMSS.org/COVID](http://www.HIMSS.org/COVID); <https://www.himss.org/news/coronavirus>