ConnectedHealth

KEY POLICY ACTIONS & GUIDANCE re COVID-19 & Digital Health

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What We Have

GUIDELINES FOR OPENING UP AMERICA AGAIN
https://www.whitehouse.gov/openingamerica/

RECOMMENDATIONS FOR RE-OPENING FACILITIES TO PROVIDE NON-EMERGENCT NON-COVID-19 HEALTHCARE: PHASE 1
https://www.cms.gov/files/document/covid-flexibility-reopen-essential-non-covid-services.pdf

CMS EMERGENCY WAIVER RESOURCES

1. https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
2. https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

CMS FAQs

1. Medicare Fee-for-Service (FFS) Billing: https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf
2. April 2020 Updates: https://www.cms.gov/files/document/provider-burden-relief-faqs.pdf

HHS TELEHEALTH RESOURCE
https://telehealth.hhs.gov/

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

CMS LONG-TERM CARE NURSING HOMES TELEHEALTH AND TELEMEDICINE TOOL KIT
https://www.cms.gov/files/document/covid-19-nursing-home-telehealth-toolkit.pdf

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

CMS NURSING HOMES TOOL KIT
https://www.cms.gov/files/document/covid-toolkit-states-mitigate-covid-19-nursing-homes.pdf

CMS INNOVATION CENTER MODELS COVID-19 RELATED ADJUSTMENTS
https://www.cms.gov/files/document/covid-innovation-model-flexibilities.pdf

HHS STATE MEDICAID & CHIP TELEHEALTH TOOLKIT

1. Toolkit: https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf
2. Supplement (Policy Considerations for States Expanding Use of Telehealth): https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit-supplement1.pdf

HHS STATE MEDICAID & CHIP FAQ

https://www.medicaid.gov/state-resource-center/downloads/covid-19-new-faqs.pdf

HHS COVID-19 STATE & LOCAL WORKFORCE TOOLKIT

https://asprtracie.hhs.gov/Workforce-Virtual-Toolkit

HHS AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) RESOURCES

https://asprtracie.hhs.gov/Workforce-Virtual-Toolkit

AMBULATORY CARE SETTINGS

- The CDC has provided the following recommendations to ambulatory care settings to avoid COVID-19 community transmissions through the increased use of telehealth:
  - Healthcare facilities can increase the use of telephone management and other remote methods of triaging, assessing, and caring for all patients to decrease the volume of persons seeking care in facilities.
  - If a formal telehealth system is not available, healthcare providers can still communicate with patients by telephone instead of in-person visits which will reduce the number of those who seek face-to-face care.
  - Health plans, healthcare systems, and insurers/payors should communicate with beneficiaries to promote the availability of covered telehealth, telemedicine, or nurse advice line services.
- Link: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ambulatory-care-settings.html

BROADBAND CONNECTIVITY

- **Keep Americans Connected Pledge**: 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

- **Waiver of Spectrum Use Requirements**: The FCC waived 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)

- **FCC COVID-19 Telehealth Program**: The FCC has allocated $200 million provided by Congress for a "COVID-19 Telehealth Program" that immediately supports eligible healthcare providers responding to the pandemic by supporting connected care services through funding telecommunications services, information services, and devices necessary to enable telehealth and telemedicine services during this emergency period.

Link: https://www.fcc.gov/covid-19-telehealth-program
Application Guidance Link: https://docs.fcc.gov/public/attachments/DA-20-394A1.pdf
Invoicing Guidance Link: https://www.fcc.gov/document/invoicing-guidance-covid-19-telehealth-program

- **Waiver of "Red Light" Rule for COVID-19 Telehealth Program Applicants**: By waving the "red light" rule for COVID-19 Telehealth Program applicants, otherwise viable telehealth projects will not be turned away due to delinquent FCC debt.
  Link: https://www.fcc.gov/document/waiver-red-light-rule-covid-19-telehealth-program
- **Waiver of Gift Rules**: 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
- **Extension of Rural Healthcare Program Application Deadline**: On March 26, the FCC's Wireline Competition Bureau took the following actions: (1) issued an extension of the RHC Program application filing window until June 30, 2020; (2) eased competitive bidding requirements for health care providers with expiring evergreen contracts; and (3) extended deadlines for responses to inquiries from the Universal Service Administrative Company, filing invoices, and filing appeals, among other deadlines.
  Link: https://www.fcc.gov/document/fcc-provides-relief-rural-health-care-program-participants

COST SHARING

- HHS' Office of the Inspector General (OIG) has issued a Policy Statement to notify physicians and other practitioners that they will not be subject to administrative sanctions for reducing or waiving any cost-sharing obligations Federal health care program beneficiaries may owe for telehealth services furnished consistent with the then-applicable coverage and payment rules, subject to certain conditions.
  - Link: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf
- OIG has supplemented this announcement with a FAQ noting that it applies to "a broad category of non-face-to-face services furnished through various modalities, including telehealth visits, virtual check-in services, e-visits, monthly remote care management, and monthly remote patient monitoring."
  - Link: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/telehealth-waiver-faq-2020.pdf

DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES (DMEPOS)

- Due to the COVID-19 pandemic, the Centers for Medicare & Medicaid Services (CMS) is removing the non-invasive ventilators (NIV) product category from Round 2021 of the DMEPOS Competitive Bidding Program. Round 2021 was the first time that Medicare had included NIVs in the DMEPOS Competitive Bidding Program. An NIV is a ventilator used with a non-invasive interface (e.g., mask) in contrast to an invasive interface (e.g., tracheostomy tube). By removing NIVs from Round 2021 of the DMEPOS Competitive Bidding Program, any Medicare-enrolled DMEPOS supplier can furnish any of the types of ventilators covered under the Medicare program.
- Link: https://www.dmecompetitivebid.com/cbic/cbic2021.nsf/DocsCat/TXYEIKZ5FH

HEALTH DATA INTEROPERABILITY & INFORMATION BLOCKING

- On April 21, ONC and CMS, in conjunction with the HHS OIG, announced a policy of enforcement discretion to allow compliance flexibilities regarding the implementation of the interoperability final rules announced on March 9th in response to the COVID-19 public health emergency. ONC will exercise enforcement discretion for 3 months at the end of certain ONC Health IT Certification Program compliance dates associated with the ONC Cures Act Final Rule. CMS will provide hospitals an additional 6 months to implement the new requirements.

- Link: https://www.hhs.gov/about/news/2020/04/21/statements-from-onc-cms-on-interoperability-flexibilities-amid-covid19-public-health-emergency.html

NEW 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.
- As a matter of enforcement discretion, effective immediately, HHS OCR will exercise its enforcement discretion and will not impose potential penalties for violations of certain provisions of the HIPAA Privacy Rule against covered health care providers or their business associates for uses and disclosures of protected health information by business associates for public health and health oversight activities during the COVID-19 nationwide public health emergency.
- As a matter of enforcement discretion, HHS OCR will not impose penalties for noncompliance with regulatory requirements under the HIPAA Rules against covered health care providers or their business associates in connection with the good faith use of online or web-based scheduling applications for the scheduling of individual appointments for COVID-19 vaccinations during the COVID-19 nationwide public health emergency.
- Links:
  - OCR Announcement: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/index.html
  - HIPAA for First Responders: https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf
  - HHS Notice of Enforcement Discretion: https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-hipaa.pdf
  - HHS Notice of Enforcement Discretion: https://www.federalregister.gov/public-inspection/2021-03348/enforcement-discretion-regarding-online-or-web-based-scheduling-applications-for-the-scheduling-of

HHS-OPERATED RISK ADJUSTMENT PROGRAM

- Any service provided through telehealth that is reimbursable under applicable state law and otherwise meets applicable risk adjustment data submission standards may be submitted to issuers' External Gathering Data Environments (EDGE) servers for purposes of the HHS-operated risk adjustment program. If a code submitted to an issuer's EDGE server is descriptive of a face-to-face service furnished by a qualified healthcare professional and is an acceptable source of new diagnoses, it will be included in the risk adjustment filtering. Telehealth visits are considered equivalent to face-to-face interactions, but are still subject to the same requirements regarding provider type and diagnostic value.
- In response to the COVID-19 pandemic and the increased need to expand the use of telehealth and virtual care, HHS will be designating 6 e-visit codes, new for calendar year 2020, as valid for 2020 benefit year HHS-operated risk adjustment data submissions subject to applicable state law requirements. This newly released group of CPT codes (99421-99423) and HCPCS codes (G2061-G2063), which were effective January 1, 2020, are generally for short online assessments where qualified healthcare professionals review patient input and determine whether an office visit is warranted. These e-visit codes allow for online evaluation and management (E&M) or professional assessment conducted via a patient portal. The CPT set is for use by physicians and other qualified health professionals who may independently bill for E&M visits. The HCPCS code set is for use by other qualified health professionals who may not be able to bill independently for E&M visits (e.g., clinical psychologists). Due to the expansion and encouragement of

telehealth and virtual services during the COVID-19 pandemic, these e -visit codes will be valid for diagnosis filtering purposes in risk adjustment data submissions for the 2020 benefit year.

- Link: https://www.cms.gov/files/document/RA-Telehealth-FAQ.pdf

HOME HEALTH AGENCIES

- Home Health Agencies (HHAs) can provide more services to beneficiaries using telecommunications technology within the 30-day period of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care. CMS acknowledges that the use of such technology may result in changes to the frequency or types of in-persons visits outlined on existing or new plans of care. Telecommunications technology can include, for example: remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology that allows for real-time interaction between the clinician and patient. However, only in-person visits can be reported on the home health claim.
- The required face-to-face encounter for home health can be conducted via telehealth (i.e., 2-way audio-video telecommunications technology that allows for real-time interaction between the physician/allowed practitioner and the patient).
- HHAs can provide more services to beneficiaries using telehealth within the 30-day episode of care, so long as it's part of the patient's plan of care and does not replace needed in-person visits as ordered on the plan of care. CMS acknowledges that the use of such technology may result in changes to the frequency or types of in-persons visits outlined on existing or new plans of care.
- CMS remains statutorily-prohibited from paying for home health services furnished via a telecommunications system if such services substitute for in-person home health services ordered as part of a plan of care and for paying directly for such services under the home health benefit. However, for the duration of the PHE for the COVID-19 pandemic, CMS is amending the regulations at § 409.43(a) on an interim basis to provide HHAs with the flexibility, in addition to remote patient monitoring, to use various types of telecommunications systems (that is, technology) in conjunction with the provision of in-person visits. Specifically, CMS is amending the regulations at § 409.43(a) on an interim basis to state that the use of technology must be related to the skilled services being furnished by the nurse/therapist/therapy assistant to optimize the services furnished during the home visit or when there is a home visit. CMS is also amending the regulations at § 409.43(a) on an interim basis to state that the use of technology must be included on the home health plan of care along with a description of how the use of such technology will help to achieve the goals outlined on the plan of care without substituting for an in-person visit as ordered on the plan of care. As a reminder, the plan of care must be signed prior to submitting a final claim to Medicare for payment (§ 409.43(c)(2)); therefore, HHAs have flexibility on the timing in which they obtain physician signatures for changes to the plan of care when incorporating the use of technology into the patient's plan of care.
- HHAs may provide services based on verbal orders in accordance with the regulations at §§ 484.60(b) and 409.43(d).
- On an interim basis HHAs can report the costs of telecommunications technology as allowable administrative and general (A&G) costs by identifying the costs using a subscript between line 5.01 through line 5.19.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- CMS Flexibilities for HHAs to Fight COVID-19: https://www.cms.gov/files/document/covid-home-health-agencies.pdf

HOSPITALS, PSYCHIATRIC HOSPITALS, & CRITICAL ACCESS HOSPITALS (CAHs), INCLUDING CANCER CENTERS AND LONG-TERM CARE HOSPITALS (LTCHs)

- CMS is waiving the provisions related to telemedicine at 42 CFR §482.12(a)(8)–(9) for hospitals and §485.616(c) for CAHs, making it easier for telemedicine services to be furnished to the hospital's patients through an agreement with an off-site hospital. This allows for increased access to necessary care for hospital and CAH patients, including access to specialty care.
- Link: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

INDIAN HEALTH SERVICE

- On March 27, IHS issued additional guidance that allowed clinicians to use certain additional, non-public facing audio or video communications technologies to augment all clinical activities related to providing care to patients during the COVID-19 public health emergency. This applied to telehealth provided for any clinical reason, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19.
- Beginning April 8, IHS service units and their clinicians who are using the system will obtain verbal consent from patients who meet with their provider via a telehealth appointment. Health care providers are required to verify the patient at the beginning of each encounter and are not authorized to record the session.
- Link: https://www.hhs.gov/about/news/2020/04/08/indian-health-service-expands-telehealth-services-during-covid-19-response.html

INPATIENT REHABILITATION FACILITY

- On an interim basis CMS is finalizing revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) during the PHE for the COVID-19 pandemic. In § 412.622(a)(3)(iv), CMS is revising this paragraph to state that physician supervision by a rehabilitation physician is required, except that during the PHE, as defined in § 400.200, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient's stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. The post-admission physician evaluation described in paragraph (a)(4)(ii) may count as one of the face-to-face visits.
  - Telehealth may be used to fulfill the requirement for physicians to conduct the required face-to-face visits at least 3 days a week for the duration of a Medicare Part A fee-for-service patient's stay in an inpatient rehabilitation facility.
- In § 412.29(e), CMS is revising this paragraph to state that a procedure must be in effect to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process, except that during the PHE, as defined in § 400.200, such visits may be conducted using telehealth services (as defined in section 1834(m)(4)(F) of the Act). CMS welcomes feedback on these revisions to the regulations at §§ 412.622(a)(3)(iv) and 412.29(e) for the duration of the PHE.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- Inpatient Rehabilitation Facilities Guidance: https://www.cms.gov/files/document/covid-inpatient-rehab-facilities.pdf

LEVEL SELECTION FOR OFFICE/OUTPATIENT E/M VISITS

- On an interim basis, CMS is revising its policy to specify that the office/outpatient E/M level selection for these services when furnished via telehealth can be based on MDM or time, with time defined as all of

the time associated with the E/M on the day of the encounter; and to remove any requirements regarding documentation of history and/or physical exam in the medical record.

- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf

MEDICAID & CHIP

- HHS has released a telehealth toolkit for Medicaid and CHIP programs. https://www.medicaid.gov/medicaid/benefits/downloads/medicaid-chip-telehealth-toolkit.pdf
- 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

MEDICAL DEVICE REGULATION

- **3D Printing Devices, Accessories, Components, and/or Parts:** The FDA released an FAQ document for entities who 3D print devices, accessories, components, and/or parts during the COVID-19 emergency. The FAQs address which PPE supplies can be made via 3-D printing, recommendations and guidance from the FDA on the uses for 3-D printed PPE, and other resources.
  Link: https://www.fda.gov/medical-devices/3d-printing-medical-devices/faqs-3d-printing-medical-devices-accessories-components-and-parts-during-covid-19-pandemic
- **Blood Glucose Monitoring Devices:** The FDA has stated that some home-use blood glucose meters have built-in wireless data transmission capabilities, which can facilitate remote patient monitoring, and has encouraged hospitals to consider policies to allow patients to self-test using home-use blood glucose meters, which may include leveraging patients' own home-use blood glucose meters or dispensing a home-use blood glucose meter upon in-patient admission to the hospital. Utilization of strategies in which hospitalized patients may conduct their own blood glucose testing, while allowing wireless access to results by health care professionals, may limit the number of necessary patient contacts, thereby reducing risk of viral transmission and preserving a hospital's limited supply of PPE.
  Link: https://www.fda.gov/medical-devices/blood-glucose-monitoring-devices/faqs-home-use-blood-glucose-meters-utilized-within-hospitals-during-covid-19-pandemic
- **Clinical Electronic Thermometers:** The FDA issued guidance on clinical electronic thermometers that immediately went into effect. Fever is a common symptom of COVID-19 and clinical electronic thermometers are an important screening and diagnostic tool to assist in the identification of those individuals who may be infected with COVID-19. The policy set forth in the guidance may help expand the availability of clinical electronic thermometers to address this public health emergency.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-clinical-electronic-thermometers-during-coronavirus-disease-2019-covid-19-public
- **Digital Health Technologies (e.g., Apps and Software Systems):** The FDA has issued a statement recognizing that digital health technologies can provide powerful tools for public health officials and the public in the management of the COVID-19 response by helping public health officials reach and communicate with a vast number of people more quickly, efficiently, and effectively. FDA identifies many

software functions that are not regulated as medical devices, including some that may be useful in the response to COVID-19.
Link: https://www.fda.gov/medical-devices/digital-health/digital-health-policies-and-public-health-solutions-covid-19

- **Digital Health Therapeutic Devices:** The FDA has issued guidance to provide a policy to help expand the availability of digital health therapeutic devices for psychiatric disorders to facilitate consumer and patient use while reducing user and healthcare provider contact and potential exposure to COVID-19 during this pandemic.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease
- **Digital Pathology Devices:** The FDA has issued guidance for "digital pathology devices" which may be used during the COVID-19 public health emergency when they are intended for use in remote reviewing and reporting of digital pathology slides.
  Link: https://www.fda.gov/media/137307/download
- **Emergency Use Authorizations (EUAs) for Medical Devices:** The FDA is using its Emergency Use Authorization (EUA) authority to allow the use of unapproved medical products, or unapproved uses of approved medical products, to diagnose, treat, or prevent serious or life-threatening diseases when certain criteria are met, including that there are no adequate, approved, and available alternatives.
  Link: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic
- **Infusion Pumps and Accessories:** The FDA issued guidance on infusion pumps and accessories that immediately went into effect. The guidance aims to help ensure the availability of infusion pumps and accessories for patients who require continuous infusion of medications, nutrition, and other fluids and help foster technologies, such as remote capabilities, that maintain a safer physical distance between the health care provider and the patient.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-infusion-pumps-and-accessories-during-coronavirus-disease-2019-covid-19-public
- **Medical X-Ray, Ultrasound, Magnetic Resonance Imaging Systems, and Image Analysis Software:** FDA has issued guidance to provide a policy to help expand the availability and capability of medical x-ray, ultrasound, magnetic resonance imaging systems, and image analysis software that are used to diagnose and monitor medical conditions while mitigating circumstances that could lead to patient, healthcare provider, and healthcare technology management (HTM) exposure to COVID-19 for the duration of the public health emergency.
  Link: https://www.fda.gov/media/137290/download
- **Non-Invasive Fetal and Maternal Monitoring Devices:** FDA has issued guidance to provide a policy to help expand the availability and capability of non-invasive fetal and maternal monitoring devices to facilitate patient monitoring while reducing patient and healthcare provider contact and potential exposure to COVID-19 during this pandemic.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-fetal-and-maternal-monitoring-devices-used-support-patient
- **Non-Invasive Remote Monitoring Devices:** The FDA has issued guidance (updated as of June 5, 2020) 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.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-non-invasive-remote-monitoring-devices-used-support-patient-monitoring-during

- FDA has issued an Emergency Use Authorization (EUA) for the Philips IntelliVue Patient Monitors for use by healthcare professionals in the hospital environment for remote monitoring of adult, pediatric, and neonate patients having or suspected of having COVID-19 to reduce healthcare provider exposure to COVID-19.
  Link: https://www.fda.gov/media/137226/download

- **Remote Ophthalmic Assessment and Monitoring Devices:** The FDA issued guidance for remote ophthalmic assessment and the use of monitoring devices. These devices include visual acuity charts, visual field devices, general use ophthalmic cameras, and tonometers. The guidance will help expand the capability of remote ophthalmic assessment and monitoring devices to facilitate patient care while reducing patient and healthcare provider contact and exposure to COVID-19.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-remote-ophthalmic-assessment-and-monitoring-devices-during-coronavirus-disease
- **Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency:** The FDA has issued guidance to help foster the continued availability of medical devices during the COVID-19 public health emergency. As described in the guidance, the FDA does not intend to object to limited modifications to the design and manufacturing of devices approved through either a PMA or HDE without prior submission of a PMA or HDE supplement or 30-day notice for the duration of the public health emergency. The policy set forth in the guidance does not apply to design or manufacturing changes made for reasons other than addressing manufacturing limitations or supply chain issues resulting from the COVID-19 public health emergency or to any proposed changes described in a regulatory submission already received by FDA.
  Link: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/supplements-approved-premarket-approval-pma-or-humanitarian-device-exemption-hde-submissions-during
- **COVID MyStudies Application (App):** The FDA The U.S. Food and Drug Administration is making its previously developed FDA MyStudies app available to investigators as a free platform to obtain informed consent securely from patients for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures. The agency is providing this resource after hearing that investigators were having difficulties obtaining informed consent for clinical trials when patients were in isolation rooms in health care facilities or could not travel to outpatient clinics.
  Link: https://www.fda.gov/drugs/science-and-research-drugs/covid-mystudies-application-app

MEDICAL PROFESSIONAL SUPERVISION & TEACHING

- On an interim basis for the duration of the PHE for the COVID-19 pandemic, CMS is altering the definition of direct supervision at § 410.32(b)(3)(ii) to state that necessary presence of the physician for direct supervision includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. CMS is revising § 410.32(b)(3)(ii) to include, during a PHE, as defined in § 400.200 of this chapter, the presence of the physician includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.
- CMS is adopting similar changes in the regulations at § 410.28(e)(1) with respect to the supervision of diagnostic services furnished directly or under arrangement in the hospital or in an on-campus or off-campus outpatient department of the hospital, as defined in § 413.65.
- CMS is adopting a similar change under § 410.27(a)(1)(iv)(D), for the duration of the PHE for the COVID-19 pandemic, to specify that direct supervision for these services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider.

- To increase the capacity of teaching settings to respond to the PHE for the COVID-19 pandemic as more practitioners are increasingly being asked to assist with the COVID-19 response, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, CMS is amending the teaching physician regulations to allow that as a general rule under § 415.172, the requirement for the presence of a teaching physician can be met, at a minimum, through direct supervision by interactive telecommunications technology, as described in section II.E. of this IFC.
- On an interim basis for the duration of the PHE for the COVID-19 pandemic, CMS is revising its regulations to specify that Medicare may make payment under the PFS for teaching physician services when a resident furnishes telehealth services to beneficiaries under direct supervision of the teaching physician which is provided by interactive telecommunications technology. Additionally, on an interim basis, for the duration of the PHE for the COVID-19 pandemic, Medicare may make payment under the PFS for services billed under the primary care exception by the teaching physician when a resident furnishes telehealth services to beneficiaries under the direct supervision of the teaching physician by interactive telecommunications technology. CMS also seeks comment on its belief that direct supervision by interactive telecommunications technology is appropriate in the context of this PHE, as well as whether and how it balances risks that might be introduced for beneficiaries with reducing exposure risk and the increased spread of the disease, in the context of this PHE.
- On an interim basis, for the duration of the PHE for the COVID19 pandemic, Medicare may also make payment under the PFS for teaching physician services when the resident is furnishing these services while in quarantine under direct supervision of the teaching physician by interactive telecommunications technology.
- On an interim basis, for the duration of the PHE for the COVID-19 pandemic, CMS is amending its regulation in § 415.208 to state that the services of residents that are not related to their approved GME programs and are performed in the inpatient setting of a hospital in which they have their training program are separately billable physicians' services for which payment can be made under the PFS provided that the services are identifiable physicians' services and meet the conditions of payment for physicians' services to beneficiaries in providers in § 415.102(a), the resident is fully licensed to practice medicine, osteopathy, dentistry, or podiatry by the State in which the services are performed, and the services are not performed as part of the approved GME program.
- During the COVID-19 PHE, teaching physicians may use audio/video real-time communications technology to interact with the resident through virtual means, which would meet the requirement that they be present for the key portion of the service, including when the teaching physician involves the resident in furnishing Medicare Telehealth services. Teaching physicians involving residents in providing care at primary care centers can provide the necessary direction, management and review for the resident's services using audio/video real-time communications technology. Residents furnishing services at primary care centers may furnish an expanded set of services to beneficiaries, including levels 4-5 of an office/outpatient evaluation and management (E/M) visit, telephone E/M, care management, and communication technology-based services. These flexibilities do not apply in the case of surgical, high risk, interventional, or other complex procedures, services performed through an endoscope, and anesthesia services. This allows teaching hospitals to maximize their workforce to safely take care of patients.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- Teaching Hospitals, Teaching Physicians and Medical Residents: https://www.cms.gov/files/document/covid-teaching-hospitals.pdf

MEDICARE ADVANTAGE ORGANIZATIONS & PARD D SPONSORS

- CMS is exercising enforcement discretion to allow Medicare Advantage plans to expand telehealth services and other mid-year benefit enhancements beyond those included in their approved 2020 benefits when such mid-year benefit enhancements are provided in connection with the COVID-19 outbreak, are beneficial to enrollees, and are provided uniformly to all similarly situated enrollees.

- Medicare Advantage Organizations may provide enrollees access to Medicare Part B services via telehealth in any geographic area and from a variety of places, including beneficiaries' homes. In response to the unique circumstances resulting from the outbreak of COVID-19, should a Medicare Advantage Organization wish to expand coverage of telehealth services beyond those approved by CMS in the plan's benefit package for similarly situated enrollees impacted by the outbreak, CMS will exercise its enforcement discretion regarding the administration of Medicare Advantage Organizations' benefit packages as approved by CMS until it is determined that the exercise of this discretion is no longer necessary in conjunction with the COVID-19 outbreak. CMS consulted with the HHS OIG and HHS OIG advised that should a Medicare Advantage Organization choose to expand coverage of telehealth benefits, as approved by CMS herein, such additional coverage would satisfy the safe harbor to the Federal anti-kickback statute set forth at 42 CFR 1001.952(l).
- Medicare Advantage plans may waive or reduce cost-sharing for beneficiaries affected by the pandemic, including waiving or reducing cost-sharing for COVID-19 testing. CMS is also exercising enforcement discretion to allow Medicare Advantage plans to expand telehealth services beyond those included in their approved 2020 benefits.
- CMS is stating that Medicare Advantage (MA) organizations and other organizations that submit diagnoses for risk-adjusted payment are able to submit diagnoses for risk adjustment that are from telehealth visits when those visits meet all criteria for risk adjustment eligibility, which include being from an allowable inpatient, outpatient, or professional service, and from a face-to-face encounter. This use of diagnoses from telehealth services applies both to submissions to the Risk Adjustment Processing System (RAPS), and those submitted to the Encounter Data System (EDS). Diagnoses resulting from telehealth services can meet the risk adjustment face-to-face requirement when the services are provided using an interactive audio and video telecommunications system that permits real-time interactive communication. While MA organizations and other organizations that submit diagnoses for risk-adjusted payment identify which diagnoses meet risk adjustment criteria for their submissions to RAPS, MA organizations (and other organizations as required) report all the services they provide to enrollees to the encounter data system and CMS identifies those diagnoses that meet risk adjustment filtering criteria. In order to report services to the EDS that have been provided via telehealth, use place of service code "02" for telehealth or use the CPT telehealth modifier "95" with any place of service.
- Link: https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf; https://www.cms.gov/files/document/covid-ma-and-part-d.pdf
- Link: https://www.cms.gov/files/document/updated-guidance-ma-and-part-d-plan-sponsors-42120.pdf

MEDICARE COMMUNICATIONS TECHNOLOGY-BASED SERVICES

- On an interim basis, during the PHE for the COVID-19 pandemic, CMS is finalizing that CTBS, which may only be reported if they do not result in a visit, including a telehealth visit, can be furnished to both new and established patients. CMS is finalizing on an interim basis during the PHE for the COVID-19 pandemic that, while consent to receive these services must be obtained annually, it may be obtained at the same time that a service is furnished (may be obtained by auxiliary staff under general supervision, as well as by the billing practitioner). CMS is retaining the requirement that in instances when the brief communication technology-based service originates from a related E/M service (including one furnished as a telehealth service) provided within the previous 7 days by the same physician or other qualified health care professional, that this service would be considered bundled into that previous E/M service and would not be separately billable.
- CMS is clarifying that there are several types of practitioners who could bill for HCPCS codes G2061-G2063 services.
    - CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- **Remote Patient Monitoring** (CPT codes 99453, 99454, 99457, and 99458)

- In response to the PHE for the COVID-19 pandemic, CMS is finalizing on an interim basis, that RPM services can be furnished to new patients, as well as to established patients.
- CMS is finalizing on an interim basis that consent to receive RPM services can be obtained once annually, including at the time services are furnished, during the duration of the PHE for the COVID-19 pandemic.
- CMS is clarifying that RPM codes can be used for physiologic monitoring of patients with acute and/or chronic conditions. The typical patient needing RPM services may have a chronic condition (for example, high blood pressure, diabetes, COPD). However, RPM can be used for other conditions. For example, RPM services allow a patient with an acute respiratory virus to monitor pulse and oxygen saturation levels using pulse oximetry. Nurses, working with physicians, can check-in with the patient and then using patient data, determine whether home treatment is safe, all the while reducing exposure risk and eliminating potentially unnecessary emergency department and hospital visits.
- Clinicians can provide remote patient monitoring services to both new and established patients. These services can be provided for both acute and chronic conditions and can now be provided for patients with only one disease. For example, remote patient monitoring can be used to monitor a patient's oxygen saturation levels using pulse oximetry. (CPT codes 99091, 99457-99458, 99473-99474, 99493-99494)
- Current CPT coding guidance states that the remote physiologic monitoring service described by CPT code 99454 (device(s) supply with daily recordings or programmed alerts transmission each 30 day(s)), cannot be reported for monitoring of less than 16 days. For purposes of treating suspected COVID-19 infections, Medicare will allow the service to be reported for shorter periods of time than 16 days as long as the other code requirements are met.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- Physician Guidance: https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.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.
  - On an interim basis, during the PHE for the COVID-19 pandemic, CMS is also broadening the availability of HCPCS codes G2010 and G2012 that describe remote evaluation of patient images/video and virtual check-ins. CMS recognizes that in the context of the PHE for the COVID-19 pandemic, practitioners such as licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech-language pathologists might also utilize virtual check-ins and remote evaluations instead of other, in-person services within the relevant Medicare benefit to facilitate the best available appropriate care while mitigating exposure risks. CMS notes that this is not an exhaustive list and is seeking input on other kinds of practitioners who might be furnishing these kinds of services as part of the Medicare services they furnish in the context of the PHE for the COVID-19 pandemic.
  - Medicare patients may have a brief communication service with practitioners via a number of communication technology modalities including synchronous discussion over a telephone or exchange of information through video or image. Clinicians can provide remote evaluation of

patient video/images and virtual check-in services (HCPCS codes G2010, G2012) to both new and established patients. These services were previously limited to established patients.
    - 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
    - CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.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.
    - To facilitate billing of the CTBS services by therapists for the reasons described above, CMS is designating HCPCS codes G2010, G2012, G2061, G2062, or G2063 as CTBS "sometimes therapy" services that would require the private practice occupational therapist, physical therapist, and speech-language pathologist to include the corresponding GO, GP, or GN therapy modifier on claims for these services. CTBS therapy services include those furnished to a new or established patient that the occupational therapist, physical therapist, and speech-language pathologist practitioner is currently treating under a plan of care.
    - Licensed clinical social workers, clinical psychologists, physical therapists, occupational therapists, and speech language pathologists can provide e-visits. E-visits are non-face-to-face communications with their practitioner by using online patient portals. (HCPCS codes G2061-G2063).
    - 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
    - CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf

MEDICARE DIABETES PREVENTION PROGRAM (MDPP)

- For suppliers and beneficiaries enrolled in the benefit as of the beginning of the public health emergency, CMS is making the following temporary changes to MDPP:
    - Increase the number of virtual make-up sessions that can be offered by MDPP suppliers.
    - Allow MDPP suppliers that have the capability, to deliver certain sessions virtually.
    - Waive the once per lifetime benefit and allow MDPP beneficiaries whose sessions were suspended to resume sessions or start over.
- Link: https://www.cms.gov/files/document/covid-medicare-diabetes-prevention-program.pdf

MEDICARE HOSPICE BENEFIT

- Hospice providers can provide services to a Medicare patient receiving routine homecare through telecommunications technology (e.g., remote patient monitoring; telephone calls (audio only and TTY); and 2-way audio-video technology), if it is feasible and appropriate to do so. Only in-person visits are to be recorded on the hospice claim.

- Face-to-face encounters for purposes of patient recertification for the Medicare hospice benefit can now be conducted via telehealth (i.e., 2-way audio-video telecommunications technology that allows for real-time interaction between the hospice physician/hospice nurse practitioner and the patient).
- CMS is amending the regulations at § 418.22(a)(4) on an interim basis to allow the use of telecommunications technology by the hospice physician or NP for the face-to-face visit when such visit is solely for the purpose of recertifying a patient for hospice services during the PHE for the COVID-19 pandemic. Telecommunications technology refers to the use of multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient (from home, or any other site permissible for receiving services under the hospice benefit) and distant site hospice physician or hospice NP. Such encounters solely for the purpose of recertification would not be a separately billed service, but rather considered an administrative expense. CMS requests feedback on the amendments to the face-to-face visit requirement for hospice recertification during the PHE for the COVID-19 pandemic.
- Link: https://www.cms.gov/files/document/faqs-telehealth-covid-19.pdf; https://www.cms.gov/files/document/covid-hospices.pdf

MEDICARE SHARED SAVINGS PROGRAM

- ACOs and their participating health care providers are using telehealth visits to continue to coordinate and deliver high quality care to their assigned beneficiaries. Consequently, for performance year 2020 and any subsequent performance year that starts during the PHE, CMS is including additional codes within the definition of primary care services used in determining beneficiary assignment under the Shared Savings Program so it can appropriately assign beneficiaries to ACOs based on remotely provided primary care services. Specifically, when performing claims-based assignment, CMS will include services billed by an ACO professional consistent with its current definition of primary care services in §425.400, but will also include remote evaluation of patient video/images HCPCS code G2010 and virtual check-in HCPCS code G2012, online digital evaluation and management services (e-visit)CPT codes 99421, 99422 and99423, and telephone evaluation and management service CPT codes 99441, 99442, and 99443.
- Link: https://www.cms.gov/files/document/covid-ifc-2-medicare-shared-savings-program.pdf

MEDICARE TELEHEALTH SERVICES

- CMS is adding 11 new services to the Medicare telehealth services list since the publication of the May 1, 2020, COVID-19 Interim Final Rule with comment period (IFC). Medicare will begin paying eligible practitioners who furnish these newly added telehealth services effective immediately, and for the duration of the PHE. These new telehealth services include certain neurostimulator analysis and programming services, and cardiac and pulmonary rehabilitation services. The list of these newly added services is available at: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
- CMS is allowing the use of audio-only equipment to furnish services described by the codes for audio-only telephone evaluation and management services, and behavioral health counseling and educational services (see designated codes https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes). Unless provided otherwise, other services included on the Medicare telehealth services list must be furnished using, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.
- 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. CMS is instructing physicians and practitioners who bill for Medicare telehealth services to report the point-of-service (POS) code that would have been reported had the service been furnished in person. This will allow CMS' systems to make appropriate payment for services furnished via Medicare telehealth which, if not for the PHE for the COVID-19 pandemic, would have been furnished in person, at the same rate they would have been paid if the services were furnished in person. Given the potential importance of using telehealth services as means of minimizing exposure risks for patients, practitioners, and the community at large, CMS believes this interim change will maintain overall relativity under the PFS for similar services and eliminate potential financial deterrents to the clinically appropriate use of telehealth. Because CMS currently use the POS code on the claim to identify Medicare telehealth services, it is finalizing on an interim basis the use of the CPT telehealth modifier, modifier 95, which should be applied to claim lines that describe services furnished via telehealth. CMS is maintaining the facility payment rate for services billed using the general telehealth POS code 02, should practitioners choose, for whatever reason, to maintain their current billing practices for Medicare telehealth during the PHE for the COVID-19 pandemic.
- To better serve the patient population that would otherwise not have access to clinically appropriate in-person treatment, the following services no longer have limitations on the number of times they can be provided by Medicare telehealth:
    - A subsequent inpatient visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every three days (CPT codes 99231-99233).
    - A subsequent skilled nursing facility visit can be furnished via Medicare telehealth, without the limitation that the telehealth visit is once every 30 days (CPT codes 99307-99310).
    - Critical care consult codes may be furnished to a Medicare beneficiary by telehealth beyond the once per day limitation (CPT codes G0508-G0509).
- To the extent that a National Coverage Determination (NCD) or Local Coverage Determination (LCD) would otherwise require a face-to-face visit for evaluations and assessments, clinicians would not have to meet those requirements during the public health emergency.
- Beneficiary consent should not interfere with the provision of non-face-to-face services. Annual consent may be obtained at the same time, and not necessarily before the time, that services are furnished.
- CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- Patient counseling and therapy services can be provided by telephone only in cases where the beneficiary does not have access to two-way interactive audio-video communication technology. Periodic patient assessments can be conducted via two-way interactive audio-video communication technology and may be provided by telephone only in cases where the beneficiary does not have access to two-way interactive audio-video communication technology.
- On an interim basis, CMS is adding a range of new services to the Medicare telehealth list on a Category 2 basis for the duration of this PHE for the COVID-19 pandemic, for telehealth services with dates of service beginning March 1, 2020 through the end of the declared PHE including any subsequent renewals.
- CMS is adding CPT code 77427 (Radiation treatment management, 5 treatments) to the telehealth list so that the required face-to-face visit can be furnished via telehealth.
- Telehealth may be used to fulfill the requirement for physicians to conduct the required face-to-face visits at least 3 days a week for the duration of a Medicare patient's stay in an inpatient rehabilitation facility.
- On an interim basis, CMS is removing the frequency restrictions for listed codes for subsequent inpatient visits and subsequent NF visits furnished via Medicare telehealth for the duration of the PHE for the COVID-19 pandemic.

- ESRD:
    - For Medicare patients with End Stage Renal Disease (ESRD), clinicians no longer must have one "hands on" visit per month for the current required clinical examination of the vascular access site.
    - For Medicare patients with ESRD, CMS is exercising enforcement discretion on the following requirement so that clinicians can provide this service via telehealth: individuals must receive a face-to-face visit, without the use of telehealth, at least monthly in the case of the initial 3 months of home dialysis and at least once every 3 consecutive months after the initial 3 months.
    - On an interim basis in light of the PHE for the COVID-19 pandemic, CMS is permitting required ESRD clinical examinations to be furnished as Medicare telehealth services during the PHE for the COVID-19 pandemic, and allowing certain ESRD visits to be furnished without the use of telehealth for services furnished during the PHE. CMS is modifying the requirement that requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement fora monthly in-person visit if the patient is considered stable and also recommends exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.
    - CMS is modifying two requirements related to care planning, specifically:
        - §494.90(b)(2): CMS is modifying the requirement which requires the dialysis facility to implement the initial plan of care within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. This modification will also apply to the requirement for monthly or annual updates of the plan of care within 15 days of the completion of the additional patient assessments. CMS is waiving the time requirement for plan of care implementation during the time period of the national emergency.
        - §494.90(b)(4): CMS is modifying the requirement which requires the ESRD dialysis facility to ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, and periodically while the hemodialysis patient is receiving in-facility dialysis. CMS is waiving the requirement for a monthly in-person visit if the patient is considered stable and also recommend exercising telehealth flexibilities, e.g. phone calls, to ensure patient safety.
    - CMS is waiving the requirement at 494.100(c)(1)(i) which requires the periodic monitoring of the patient's home adaptation, including visits to the patient's home by facility personnel. For more information on existing flexibilities for in-center dialysis patients to receive their dialysis treatments in the home, or long-term care facility, reference QSO-20-19-ESRD.
    - More detail: https://www.cms.gov/files/document/covid-19-esrd-facilities.pdf
    - More detail: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf
- For the duration of the public health emergency, as defined in § 400.200 of this chapter, *Interactive telecommunications system* means multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.
- 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 will now allow more than 80 additional services to be furnished via telehealth. This expanded reimbursement for telehealth services to Medicare beneficiaries will be valid after March 1, 2020 and for the duration of the PHE.
- CMS is waiving the requirement in 42 CFR 483.30 for physicians and non-physician practitioners to perform in-person visits for nursing home residents and allow visits to be conducted, as appropriate, via telehealth options.
- CMS is waiving the requirements of section 1834(m)(4)(E) of the Act and 42 CFR § 410.78 (b)(2) which specify the types of practitioners that may bill for their services when furnished as Medicare telehealth services from the distant site. The waiver of these requirements expands the types of health care professionals that can furnish distant site telehealth services to include all those that are eligible to bill Medicare for their professional services. This allows health care professionals who were previously ineligible to furnish and bill for Medicare telehealth services, including physical therapists, occupational therapists, speech language pathologists, and others, to receive payment for Medicare telehealth services.
- When a physician or nonphysician practitioner who typically furnishes professional services in the hospital outpatient department furnishes telehealth services during the COVID-19 PHE, they bill with a hospital outpatient place of service since that is likely where the services would have been furnished if not for the COVID-19 PHE. The physician or practitioner is paid for the service under the PFS at the facility rate, which does not include payment for resources such as clinical staff, supplies, or office overhead since those things are usually supplied by the hospital outpatient department. During the COVID-19 PHE, if the beneficiary's home or temporary expansion site is considered to be a provider-based department of the hospital, and the beneficiary is registered as an outpatient of the hospital for purposes of receiving telehealth services billed by the physician or practitioner, the hospital may bill under the PFS for the originating site facility fee associated with the telehealth service.
- 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
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- CMS 2nd Interim Final Rule: https://www.cms.gov/files/document/covid-medicare-and-medicaid-ifc2.pdf
- COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf
- List of Telehealth Services: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes
- Physician Guidance: https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf
- CMS Billing for Professional Telehealth Distant Site Services During the PHE: https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2020-03-31-mlnc-se#_Toc36550823
- HRSA Guidance: https://bphc.hrsa.gov/emergency-response/coronavirus-frequently-asked-questions.html

MEDICARE TELEPHONE EVALUATION, MANAGEMENT/ASSESSMENT AND MANAGEMENT SERVICES, AND BEHAVIORAL HEALTH AND EDUCATION SERVICES

  - Medicare payment for the telephone evaluation and management visits (CPT codes 99441-99443) is equivalent to the Medicare payment for office/outpatient visits with established patients effective March 1, 2020.
  - When clinicians are furnishing an evaluation and management (E/M) service that would otherwise be reported as an in-person or telehealth visit, using audio-only technology, practitioners may bill using these

telephone E/M codes provided that it is appropriate to furnish the service using audio-only technology and all of the required elements in the applicable telephone E/M code (99441-99443) description are met.

- Using new waiver authority, CMS is also allowing many behavioral health and education services to be furnished via telehealth using audio-only communications. The full list of telehealth services notes which services are eligible to be furnished via audio-only technology, including the telephone evaluation and management visits: https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
- CMS is finalizing, on an interim basis for the duration of the PHE for the COVID-19 pandemic, separate payment for CPT codes 98966-98968 and CPT codes 99441-99443. For these codes, CMS is finalizing on an interim basis for the duration of the PHE for the COVID-19 pandemic, work RVUs as recommended by the AMA Health Care Professionals Advisory Committee (HCPAC) for CY PFS 2008 rulemaking as discussed in the CY 2008 PFS final rule (72 CFR 66371) of 0.25 for CPT code 98966, 0.50 work RVUs for CPT code 98967, and 0.75 for CPT code 98968, and work RVUs as recommended by the AMA Relative Value Scale Update Committee (RUC) of 0.25 for CPT code 99441, 0.50 for CPT code 99442, and 0.75 for CPT code 99443. CMS is finalizing the HCPAC and RUC-recommended direct PE inputs which consist of 3 minutes of post-service RN/LPN/MTA clinical labor time for each code.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- Physician Guidance: https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf

NATIONAL COVERAGE DETERMINATION & LOCAL COVERAGE DETERMINATION REQUIREMENTS

- On an interim basis, CMS is finalizing that to the extent an NCD or LCD (including articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the PHE for the COVID-19 pandemic.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf

PHYSICIAN SELF-REFERRAL RULES (STARK LAW)

- On March 30, 2020, CMS issued blanket waivers of sanctions under the physician self-referral law for COVID-19 Purposes, providing vital flexibility for physicians and providers in the fight against COVID-19. The waivers are effective March 1, 2020 and may be used without notifying CMS.
  - Link: https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf
- Under its waiver authority, CMS will permit certain referrals and the submission of related claims that would otherwise violate the Stark Law. These flexibilities include loosening some of the restrictions regarding when a group practice can furnish medically necessary designated health services (DHS) in a patient's home. For example, any physician in the group may order medically necessary DHS that is furnished to a patient by one of the group's technicians or nurses in the patient's home contemporaneously with a physician service that is furnished via telehealth by the physician who ordered the DHS. An entity that provides free telehealth equipment to a physician practice to facilitate telehealth visits for patients who are observing social distancing or in isolation or quarantine would fall under HHS' Stark Law waivers.
  - Link: https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.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.
- Link: https://deadiversion.usdoj.gov/coronavirus.html?inf_contact_key=e475ad72cf428bcacdb0e59dbb26b0eb680f8914173f9191b1c0223e68310bb1

PRIVATE HEALTH INSURANCE

- CMS encourages states to support efforts by health insurance issuers to increase access to telehealth services. In particular, CMS urges states to consider whether state licensing laws could be relaxed to enable more in-state and out-of-state providers to offer telehealth services in the state during the period in which a public health emergency declaration related to COVID-19 is in effect.
- In light of the public health emergency posed by COVID-19, CMS will allow issuers in the individual and group markets to amend plan benefits during a plan year to provide or expand coverage for telehealth services, and to reduce or eliminate cost sharing for such services.
- In light of the public health emergency posed by COVID-19, CMS will allow issuers of catastrophic plans to provide coverage for telehealth services before enrollees meet plan deductibles.
- Under Section 6001 of the FFCRA, items and services furnished to an individual during a healthcare provider office visit (which includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits that result in an order for or administration of an in vitro diagnostic product defined in section 809.3 of title 21, Code of Federal Regulations, (or its successor regulations) for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and the administration of such a test, but only to the extent the items and services relate to the furnishing or administration of the product or to the evaluation of the individual for purposes of determining the need of the individual for such product.
- The Centers for Disease Control and Prevention (CDC) advises that clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. In addition, the CDC strongly encourages clinicians to test for other causes of respiratory illness. Therefore, for example, if the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed during a visit (which term here includes in-person visits and telehealth visits) to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA. This coverage must be provided without cost sharing, when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice. This coverage must also be provided without imposing prior authorization or other medical management requirements.
- The term "visit" in section 6001(a)(2) of the FFCRA is to be construed broadly to include both traditional and non-traditional care settings (including telehealth visits) in which a COVID-19 diagnostic test described in section 6001(a)(1) of the FFCRA is ordered or administered, including COVID-19 drive-through screening and testing sites where licensed healthcare providers are administering COVID-19 diagnostic testing. Therefore, the items and services described in section 6001(a) of the FFCRA, as

amended by section 3201 of the CARES Act, must be covered when furnished in non-traditional settings, as well as when provided in traditional settings.

- The widespread availability and use of telehealth and other remote care services are vital to combat the COVID-19 public health emergency. By using these services, patients are able to seek treatment from a healthcare professional in their home, without having to go to a medical office or hospital, helping minimize the risk of exposure to and community spread of COVID-19. The Departments recognize that many plans and issuers are currently offering benefits for telehealth and/or other remote care services in some form. Many states have encouraged issuers to cover robust telehealth and other remote care services without cost sharing, and many plans and issuers have taken steps to promote the use of these services by providing expanded access to them without cost sharing. All plans and issuers are strongly encouraged to promote the use of telehealth and other remote care services, including by notifying consumers of their availability, by ensuring access to a robust suite of telehealth and other remote care services, including mental health and substance use disorder services, and by covering telehealth and other remote care services without cost sharing or other medical management requirements.
- An otherwise eligible individual with coverage under a high health deductible plan (HDHP) may also receive coverage for telehealth and other remote care services outside the HDHP and before satisfying the deductible of the HDHP and still contribute to a Health Savings Account (HSA). This policy is effective March 27, 2020 and applies to plan years beginning on or before December 31, 2021.
- Amendments to section 223 of the Code in the FFCRA apply generally to coverage for healthcare provided through telehealth and other remote care services and are not limited to coverage for COVID-19-related telehealth and other remote care services.
- In light of the public health emergency posed by COVID-19, plans and issuers will be allowed to add benefits, or reduce or eliminate cost sharing, for telehealth and other remote care services prior to satisfying any applicable notice of modification requirements and without regard to restrictions on mid-year changes to provide coverage for telehealth services.
- CMS FAQ Link: https://www.cms.gov/files/document/faqs-telehealth-covid-19.pdf
- DOL-HHS-Treasury FAQ: https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.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 & QUALITY REPORTING PROGRAM/VALUE-BASED PURCHASING

- 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).
- CMS has provided exceptions under certain Medicare quality reporting and value-based purchasing programs for acute care acute care hospitals, Prospective Payment System (PPS)-exempt cancer hospitals, inpatient psychiatric facilities, skilled nursing facilities, home health agencies, hospices, inpatient rehabilitation facilities, long-term care hospitals, ambulatory surgical centers, renal dialysis facilities, and

MIPS eligible clinicians for all providers and suppliers participating in the programs described below across the United States and its territories in response to the Coronavirus (COVID-19) pandemic.

- CMS has changed to include the codes for CTBS and telephone E/M services in the definition of primary care services for purposes of the MIPS beneficiary assignment methodology for the CMS Web Interface and CAHPS for MIPS survey. These codes are: (1) CPT codes: 99421, 99422, and 99423 (codes for online digital E/M service (e-visit)), and 99441, 99442, and 99443 (codes for telephone E/M services); and (2) HCPCS codes: G2010 (code for remote evaluation of patient video/images) and G2012 (code for virtual check-in).
- Links:
    - https://www.cms.gov/newsroom/press-releases/cms-announces-relief-clinicians-providers-hospitals-and-facilities-participating-quality-reporting; https://www.cms.gov/files/document/guidance-memo-exceptions-and-extensions-quality-reporting-and-value-based-purchasing-programs.pdf
    - https://www.cms.gov/files/document/covid-ifc-3-8-25-20.pdf

RURAL HEALTH CLINICS (RHCs) & FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs)

- Section 3704 of the CARES Act authorizes RHCs and FQHCs to furnish distant site telehealth services to Medicare beneficiaries during the COVID-19 PHE. Medicare telehealth services generally require an interactive audio and video telecommunications system that permits real-time communication between the practitioner and the patient. (During the PHE, some telehealth services can be furnished using audio-only technology.) RHCs and FQHCs with this capability can provide and be paid for telehealth services furnished to Medicare patients located at any site, including the patient's home, for the duration of the COVID-19 PHE. Telehealth services can be furnished by any health care practitioner working for the RHC or the FQHC within their scope of practice. Practitioners can furnish telehealth services from any distant site location, including their home, during the time that they are working for the RHC or FQHC, and can furnish any telehealth service that is included on the list of Medicare telehealth services under the Physician Fee Schedule (PFS), including those that are added on an interim basis during the PHE. A list of these services, including which can be furnished via audio-only technology, is available at https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/Telehealth-Codes.
- Practitioners can furnish distant site telehealth services from any location, including their home, during the time that they are working for the RHC or FQHC, and can furnish any telehealth service that is approved as a distant site telehealth service under the Physician Fee Schedule (PFS). A list of these is available at https://www.cms.gov/files/zip/covid-19-telehealth-services-phe.zip.
    - For telehealth distant site services furnished between January 27, 2020, and June 30, 2020, RHCs and FQHCs must put Modifier "95" (Synchronous Telemedicine Service Rendered via Real-Time Interactive Audio and Video Telecommunications System) on the claim. RHCs will be paid at their all-inclusive rate (AIR), and FQHCs will be paid based on the FQHC Prospective Payment System (PPS) rate. These claims will be automatically reprocessed in July when the Medicare claims processing system is updated with the new payment rate. RHCs and FQHCs do not need to resubmit these claims for the payment adjustment.
    - For telehealth distant site services furnished between July 1, 2020, and the end of the COVID-19 PHE, RHCs and FQHCs will use an RHC/FQHC specific G code, G2025, to identify services that were furnished via telehealth. RHC and FQHC claims with the new G code will be paid at the $92 rate. Only distant site telehealth services furnished during the COVID-19 PHE are authorized for payment to RHCs and FQHCs. If the COVID-PHE is in effect after December 31, 2020, this rate will be updated based on the 2021 PFS average payment rate for these services, weighted by volume for those services reported under the PFS.

- Costs for furnishing distant site telehealth services will not be used to determine the RHC AIR or the FQHC PPS rates but must be reported on the appropriate cost report form. RHCs must report both originating and distant site telehealth costs on Form CMS-222-17 on line 79 of the Worksheet A, in the section titled "Cost Other Than RHC Services." FQHCs must report both originating and distant site telehealth costs on Form CMS-224-14, the Federally Qualified Health Center Cost Report, on line 66 of the Worksheet A, in the section titled "Other FQHC Services."
    - Since telehealth distant site services are not paid under the RHC AIR or the FQHC PPS, the Medicare Advantage wrap-around payment does not apply to these services. Wrap-around payment for distant site telehealth services will be adjusted by the MA plans.
    - During the COVID-19 PHE, CMS will pay all of the reasonable costs for any service related to COVID-19 testing, including applicable telehealth services, for services furnished beginning on March 1, 2020. For services related to COVID-19 testing, including telehealth, RHCs and FQHCs must waive the collection of co-insurance from beneficiaries. For services in which the coinsurance is waived, RHCs and FQHCs must put the "CS" modifier on the service line. RHC and FQHC claims with the "CS" modifier will be paid with the coinsurance applied, and the Medicare Administrative Contractor (MAC) will automatically reprocess these claims beginning on July 1. Coinsurance should not be collected from beneficiaries if the coinsurance is waived.
- On an interim basis, CMS is expanding the services that can be included in the payment for HCPCS code G0071 and updating the payment rate to reflect the addition of these services. Specifically, CMS is adding CPT codes 99421 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 5-10 minutes); 99422 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 11-20 minutes); and 99423 (Online digital evaluation and management service, for an established patient, for up to 7 days, cumulative time during the 7 days; 21 or more minutes).
- CMS is revising the payment rate for HCPCS code G0071 to include the national non-facility payment rates for 99421, 99422, and 99423. Effective for services furnished on or after March 1, 2020 and throughout the PHE for the COVID pandemic, the payment rate for HCPCS code G0071 will be the average of the PFS national non-facility payment rate for HCPCS code G2012 (communication technology-based services), HCPCS code G2010 (remote evaluation services), CPT code 99421, CPT code 99422, and CPT code 99423. The RHC and FQHC face-to-face requirements are be waived for these services. Section 405.2464 (e) establishes payment for communication technology-based and remote evaluation services, and no regulatory changes are required.
- During the PHE for the COVID-19 pandemic, CMS is finalizing that all virtual communication services that are billable using HCPCS code G0071 will also be available to new patients that have not been seen in the RHC or FQHC within the previous 12 months. Also, in situations where obtaining prior beneficiary consent would interfere with the timely provision of these services, or the timely provision of the monthly care management services, during the PHE for the COVID-19 pandemic consent can be obtained when the services are furnished instead of prior to the service being furnished, but must be obtained before the services are billed. CMS will also allow patient consent to be acquired by staff under the general supervision of the RHC or FQHC practitioner for the virtual communication and monthly care management codes during the PHE for the COVID-19 pandemic. These changes are consistent with the flexibilities CMS is establishing for similar services paid under the PFS as described in section II.D. of the IFC.
    - Payment for virtual communication services now includes online digital evaluation and management services. Online digital evaluation and management services are non-face-to-face, patient-initiated, digital communications using a secure patient portal. The online digital evaluation and management codes that are billable during the COVID-19 PHE are:
        - CPT code 99421 (5-10 minutes over a 7-day period)
        - CPT code 99422 (11-20 minutes over a 7-day period)

    - CPT code 99423 (21 minutes or more over a 7-day period)

  To receive payment for the new online digital evaluation and management (CPT codes 99421, 99433, and 99423) or virtual communication services (HCPCS codes G2012 and G2010), RHCs and FQHCs must submit an RHC or FQHC claim with HCPCS code G0071 (Virtual Communication Services) either alone or with other payable services. For claims submitted with HCPCS code G0071 on or after March 1, 2020, and for the duration of the COVID-19 PHE, payment for HCPCS code G0071 is set at the average of the national non-facility PFS payment rates for these 5 codes. Claims submitted with G0071 on or after March 1 and for the duration of the PHE will be paid at the new rate of $24.76, instead of the CY 2020 rate of $13.53. MACs will automatically reprocess any claims with G0071 for services furnished on or after March 1 that were paid before the claims processing system was updated.

- CMS is modifying the requirement that physicians must provide medical direction for the clinic's or center's health care activities and consultation for, and medical supervision of, the health care staff, only with respect to medical supervision of nurse practitioners, and only to the extent permitted by state law. The physician, either in person or through telehealth and other remote communications, continues to be responsible for providing medical direction for the clinic or center's health care activities and consultation for the health care staff, and medical supervision of the remaining health care staff. This allows RHCs and FQHCs to use nurse practitioners to the fullest extent possible and allows physicians to direct their time to more critical tasks.
- CMS Interim Final Rule: https://www.cms.gov/files/document/covid-final-ifc.pdf
- CMS Flexibilities for FQHCs and RHCs to Fight COVID-19: https://www.cms.gov/files/document/covid-rural-health-clinics.pdf
- CMS MLN: https://www.cms.gov/files/document/se20016.pdf
- CMS Emergency Declaration Blanket Waivers for Health Care Providers: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

TELEHEALTH ACCESS AND INFRASTRUCTURE

- HRSA awarded $20 million to increase telehealth access and infrastructure for providers and families to help prevent and respond to COVID-19. The funds will increase capability, capacity and access to telehealth and distant care services for providers, pregnant women, children, adolescents and families, and will assist telehealth providers with cross-state licensure to improve access to health care during the pandemic.
  Link: https://www.hhs.gov/about/news/2020/04/30/hhs-awards-20-million-to-combat-covid19-pandemic-through-telehealth.html
- HRSA awarded $15 million to 159 organizations across five health workforce programs to increase telehealth capabilities in response to the COVID-19 pandemic.
  Link: https://www.hhs.gov/about/news/2020/05/13/hhs-awards-15-million-to-support-telehealth-providers-during-covid19-pandemic.html

TRICARE

- The Assistant Secretary of Defense for Health Affairs has issued an interim final rule with comment to: provide an exception to the prohibition on telephone, audio-only telehealth services; authorize reimbursement for interstate or international practice by TRICARE-authorized providers when such authority is consistent with governing state, federal, or host nation licensing requirements; and eliminate copayments and cost-shares for telehealth services. The changes in this rule are effective for the period of the COVID-19 pandemic.
  Link: https://s3.amazonaws.com/public-inspection.federalregister.gov/2020-10042.pdf

VIRTUAL CASE MANAGEMENT

- To encourage the adoption of virtual case management approaches, ASPE has provided guidance that lays out technology and practice considerations, as well as resources.
- Link: https://aspe.hhs.gov/pdf-report/virtual-case-management

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~~
- CMS enforcement discretion to eliminate face-to-face requirements for any digital health (~~telehealth, RPM~~, and home INR monitoring services [HCPCS G0248 and G0249]) service to establish a proper physician/patient relationship
- 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)
- FQHCs and RHCs should be able to furnish and bill for ~~telehealth services, as well as~~ RPM services (e.g., under the same fee-for-service carve out FQHCs and RHCs already enjoy for CCM, TCM, and BHI services).
- Prior authorization (PA):
  - Prior authorization waivers for all Medicare and commercial insurer programs
- Privacy/HIPAA:
  - ~~Direct HHS Office for Civil Rights (OCR) to exercise enforcement discretion and waiving penalties for HIPAA violations re telehealth and RPM~~
  - ~~OCR enforcement discretion of the HIPAA Security rule outside of telehealth (e.g., if a practice or hospital faces a cyber-attack and reports it to the public and OCR, OCR should not take adverse action against a practice for sharing info with government)~~
  - OCR guidance clarifying that end-to-end encrypted communications services that are limited to transmission-only where ePHI storage is on a temporary basis incident to the transmission service are conduits
  - Relaxation of state law/regulations that impede the use of non-HIPAA compliant platforms for digital health communications
- ~~CMS should modify the MA/Part D and ACO risk adjustment policy to incorporate diagnoses from telehealth encounters (currently telehealth is not "risk adjustable" as it is not a "face-to-face" visit).~~
- Allow LSWs, Clinical Psychologists, PTs/OTs/STs, and others to independently order and bill for ~~telehealth~~ and RPM services.
- 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 patients.
- Broadband availability efforts by FCC:
  - ~~New authority and allocations to support connected health during the COVID-19 emergency~~
  - ~~Advance COVID-19-focused program and Connected Care Pilot Program~~
  - Enabling new means of 5G connectivity (e.g., new spectrum use allowances, TV White Spaces deployed nationally in underserved and unserved areas, etc.)
- 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 (e.g., ~~imaging~~)

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
- Polsinelli: https://www.covid19.polsinelli.com/telehealth
- 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
- ATA: https://info.americantelemed.org/covid-19-news-resources
- Blue Cross Blue Shield: https://www.bcbs.com/coronavirus-updates
- 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
- Crowell & Moring: https://www.crowell.com/Practices/Coronavirus-COVID-19-Resource-Center/Health-Care-Resources
- Faegre Drinker: https://www.faegredrinker.com/en/insights/topics/coronavirus-covid-19-resource-center#Explore%20the%20Resource%20Center; https://www.faegredrinker.com/en/insights/publications/2020/3/a-day-in-telehealth-history
- HIMSS: www.HIMSS.org/COVID; https://www.himss.org/news/coronavirus
- Humana: http://apps.humana.com/marketing/documents.asp?file=3895073
- Molina: https://www.molinahealthcare.com/providers/fl/marketplace/forms/PDF/COVID-19-PROVIDER-NOTIFICATION.pdf
- 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
- National Governors Association: https://www.nga.org/coronavirus/
- Nixon Law Group: https://www.nixonlawgroup.com/covid-19-telehealth-and-rpm-resources
- Powers Law Group: https://www.powerslaw.com/news-events/
- United Healthcare: https://www.uhcprovider.com/en/resource-library/news/Novel-Coronavirus-COVID-19/covid19-telehealth-services.html