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Telemedicine in the COVID-19 Pandemic: What Has Changed and What Has Not

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LICENSURE AND SCOPE OF PRACTICE

Scope of Practice & Licensure Changes

- **CMS 1135 Waivers** lift many scope of practice and licensure requirements
  - 1135 waivers cannot waive state law requirements

- Michigan Governor's **Executive Order 2020-30**, issued March 29, 2020, significantly changes the landscape regarding in-state licensure and scope of practice restrictions as necessary to address the COVID-19 emergency

- These changes can be applied to **telemedicine services**

Waiver of MI License Requirement

- **E.O. 2020-30 Permits Practice by Out-of-State Licensed Health Professionals**
  - Health professionals who are licensed in good standing in other states or territories may practice in Michigan without criminal, civil or administrative/licensure penalties for lack of Michigan licensure
  - Any license subject to limitation in another state/territory is subject to the same limitation in Michigan
  - Federation of State Medical Boards maintains current information on which states permit practice by out-of-state providers at www.fsmb.org/siteassets/advocacy/pdf/state-emergency-declarations-licensures-requirementscovid-19.pdf

Scope of Practice Changes – EO 2020-30

- E.O. 2020-30 **temporarily suspends** provisions of Article 15 of the Michigan Public Health Code ("Code") relating to scope of practice, supervision and delegation as needed to allow:
  - a licensed, registered or certified health professional;
  - working as an employee/contractor in a "designated health care facility;"
  - to provide medical services necessary to support the facility's response to the COVID-19 pandemic;
  - that are appropriate to the professional's education, training and experience, as determined by the facility in consultation with its medical leadership ("Medical Services")

Scope of Practice Changes – EO 2020-30

- Examples of suspension of scope of practice, supervision and delegation provisions of law under E.O. 2020-30:
  - Physician's assistant may provide Medical Services without a physician practice agreement
  - RNs and LPNs may order COVID-19 tests
  - APRNs and CRNAs not subject to physician delegation and supervision requirements when providing Medical Services
    - Per LARA, this permits APRN to prescribe controlled substances without physician delegation

Scope of Practice Changes – EO 2020-30

- "**Designated Health Care Facility**" ("Facility") includes only the following:
  - Facilities licensed under Article 17 of the Code (e.g. hospital, nursing home, county medical facility, hospice/ hospice residence, home for the aged, freestanding surgical outpatient facility, EMT operations, HMO)
  - State-owned surgical centers
  - State-operated outpatient and veterans facilities
  - Entities used by the above as surge capacity

- Facility does not include physician offices, clinics, FQHCs

Scope of Practice Changes – EO 2020-30

- **Respiratory Therapist Extenders**
  - A Facility may allow medical students, physical therapists and emergency medical technicians to volunteer/work in the Facility as “respiratory therapist extenders”
  - Work under the supervision of physicians, respiratory therapists (“RTs”) or APRNs
  - Purpose is to assist RTs and other health care professionals in the operation of ventilators or related devices

Scope of Practice Changes – EO 2020-30

- **Protection from Liability for Health Professionals and Facilities**
  - Licensed health professionals and Facilities that provide medical services in support of the Michigan COVID-19 pandemic response are not liable for any injury sustained by a person by reason of those services
  - Protection applies regardless of how, under what circumstances, or what causes the injuries, unless the injury is caused by the health professional's or Facility's gross negligence, as defined in the Michigan Emergency Management Act ("Act")

Scope of Practice Changes – EO 2020-30

- **Use of Students**
  - Facilities may allow students enrolled in health professional licensure programs to provide Medical Services at the Facility, without need for a clinical affiliation agreement

- **Use of Volunteers**
  - Subject to any conditions set by the Director of the Michigan Department of Health and Human Services, a Facility may use qualified volunteers or personnel from other Facilities, and to adjust the volunteers' and personnel's scope of practice as though they were affiliated with the Facility

Scope of Practice Changes – EO 2020-30

- **Rights and Immunities for Students and Volunteers**
  - Unlicensed volunteers or students performing activities in support of the Michigan COVID-19 pandemic response are considered “personnel of a disaster relief force” under the Act, and are entitled to the same immunities and rights provided to state employees under the Act when providing such services

Scope of Practice Changes - Medicare

- **Supervision via telemedicine** – direct supervision may be provided virtually via real-time, audio/visual technology

- **Waiver** of requirement that **hospital patients** be **under a physician's care** – CMS allowing use of other practitioners (PA, NP, etc.) in accordance with state law

- **Waiver of National or Local Coverage Decision requirements** for use of a **specific practitioner type** – facility's chief medical officer given authority to make such staffing decisions

Scope of Practice & Licensure Changes

- **What Has Changed:**
  - Use of out-of-state licensed health care professionals permitted
  - Formal delegation and supervision requirements removed in Facilities
  - Who makes the determination of appropriate qualifications - Facility now makes determination in consultation with medical leadership
  - Liability protection for medical services provided to address COVID-19
  - Respiratory therapist extenders
  - Use of students and volunteers in a Facility

Scope of Practice & Licensure Changes

- **What has not changed:**
  - Licensees may still use “regular” delegation/supervision provisions of the Code
  - Determination of appropriate qualifications still required
  - The standard of care

Scope of Practice Changes

- Recommendations for Facilities using expanded functions:
  - **Identify Medical Leadership.** Determine and document who is “medical leadership” for your Facility
  - **Designate Expanded Tasks.** Determine and document which medical tasks necessary to address COVID-19 could be performed by qualified licensees in an expanded role
  - **Set Qualifications for Tasks.** In consultation with medical leadership, establish and document standards for “the appropriate education, training and experience” to perform expanded medical tasks in your Facility

Scope of Practice Changes

- Recommendations for Facilities using expanded functions (cont'd):
  - **Assign Expanded Tasks.** Using these qualification standards, designate and document which licensed health care professionals will be permitted to perform which expanded medical tasks in your Facility
  - **Communication.** Communicate these standards, policies and decisions clearly to all Facility staff
  - **Evaluate and Update.** Monitor, evaluate use of expanded roles frequently, and adjust determinations and policies as appropriate

PRESCRIBING

Michigan Law Requirements

- **General consent** for telehealth services
  - Under the telehealth provisions of the Code, a practitioner using telemedicine must directly or indirectly obtain the patient's consent to treat via telemedicine (MCL § 333.16284)

Michigan Law Requirements

- The Code requires a practitioner **prescribing drugs via telemedicine** to do the following (MCL § 333.16285) :
  - **Act within scope.** Practitioner must be acting within the scope of his or her practice in prescribing the drug (*including new expanded roles in Facilities*);
  - **Meet CS legal requirements.** If prescribing a controlled substance, practitioner must meet all legal requirements for prescribing a controlled substance;

Michigan Law Requirements

- The Code requires a practitioner **prescribing drugs via telemedicine** to do the following (MCL § 333.16285) (cont'd):
  - **Make referrals.** If he/she considers it medically necessary, provide the patient with a referral for other health care services that are geographically accessible to the patient, including, but not limited to, emergency services; and
  - **Follow-up.** Make himself/herself available for follow-up health care services, or refer the patient to another health professional for follow-up health care services

Michigan Law Requirements

- Compliance with **Opioid Start Talking Form** Requirements (MCL § 333.7303b and § 333.7303c)
  - **Problem**: Prescribers are unable to obtain a patient's signature on form prior to prescribing an opioid via telemedicine
  - **LARA recommends** electronic signature or sending form to patient to sign and return
  - Recommend explaining Opioid Start Talking Form during the televisit, securing patient's intention and promise to sign the form upon receipt, and documenting same in the patient's record

DEA Lifts In-Person Exam Requirement

- The federal Ryan Haight Act (the "Act") ordinarily requires prescribers to perform an in-person medical evaluation before using the Internet to prescribe controlled substances for that patient (21 USC § 829(e))

- The DEA has activated an exception in the Act for use of telemedicine to prescribe controlled substances during the COVID-19 national emergency (21 USC § 802(54)(D))
  - Removes need for an in-person medical evaluation prior to prescribing controlled substances via the Internet

DEA Lifts State Registration Requirement

- On Tuesday, March 23, 2020, the DEA issued a blanket exception from the requirement that a practitioner must be registered in each state in which he/she prescribes CS
  - This permits use of telemedicine across state lines to prescribe CS (and without in-person exam)

- The DEA's guidance can be found on the Diversion Control Division's COVID-19 Information Page, located at: https://www.deadiversion.usdoj.gov/coronavirus.html.

Prescribing via Telemedicine

- **What has changed:**
  - Expanded roles for prescribing in a Facility
  - No in-person exam requirement for controlled substance prescribing
  - Waiver of “each state” DEA registration requirement

Prescribing via Telemedicine

- **What has not changed:**
  - Michigan law requirements for informed consent, referral and follow-up care
  - Federal laws for telecommunication systems for prescribing controlled substances via the Internet
  - Requirement to complete Opioid Start Talking Form
  - MAPS reporting and query requirements
  - The standard of care

REIMBURSEMENT

Telehealth Reimbursement Landscape

- Ever evolving area (even before COVID-19)

- Medicare
- Medicaid
- Commercial Insurers
- Self-Pay / “Direct to Consumer”

CMS Expands Medicare Telehealth Reimbursement

- March 6, 2020 - Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (CPRSAA) allowed HHS to temporarily waive certain Medicare restrictions and requirements regarding the delivery of telehealth services during the COVID-19 public health emergency
- March 17, 2020 - CMS implemented telehealth waiver
- March 27, 2020 - Coronavirus Aid, Relief, and Economic Security Act (CARES Act), made changes to CPRSAA
- March 30, 2020 – CMS issues Interim Final Rule with additional blanket regulatory waivers

CMS Expands Medicare Telehealth Reimbursement

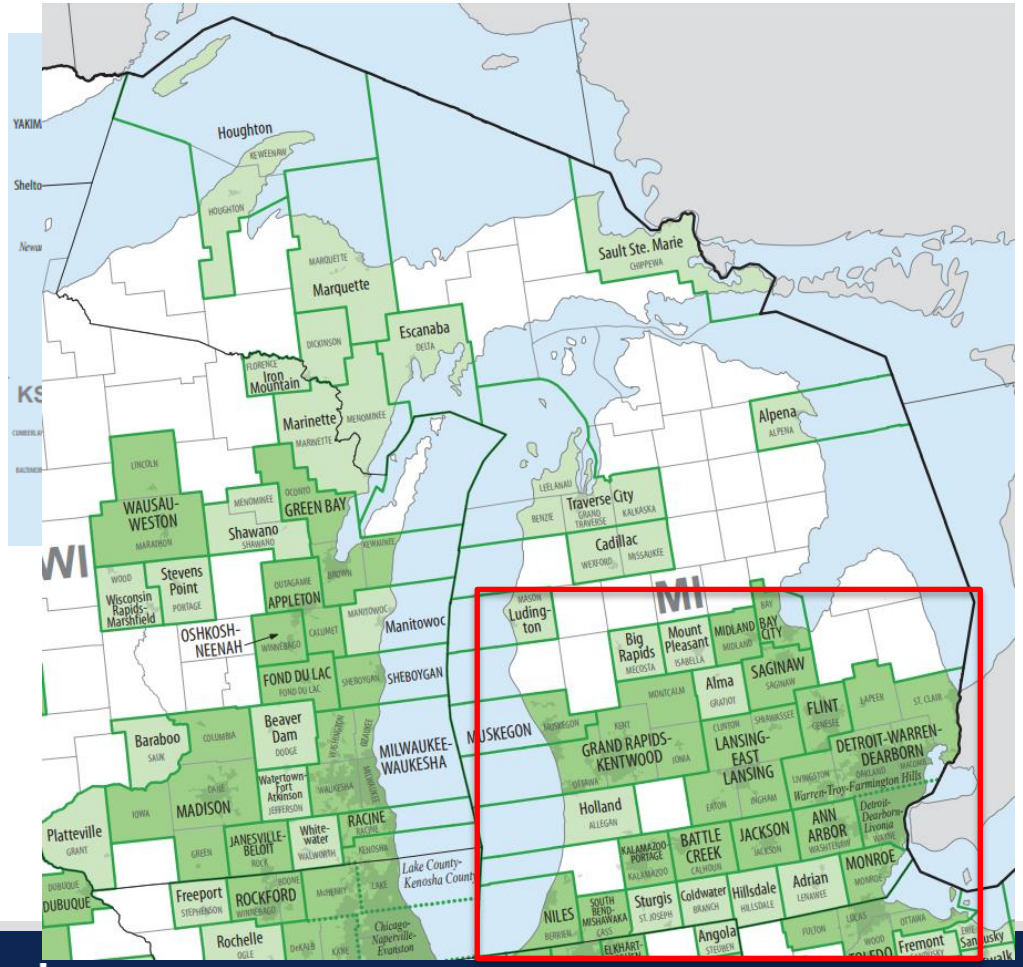
- **42 CFR § 414.65 - Payment for telehealth services**
  - Professional service
  - Originating site facility fee
  - Deductible and coinsurance apply
  - Assignment required for physicians, practitioners, and originating sites
- Medicare Claims Processing Manual, Ch. 12, § 190
- MLN Booklet, Telehealth Services (March 2020)

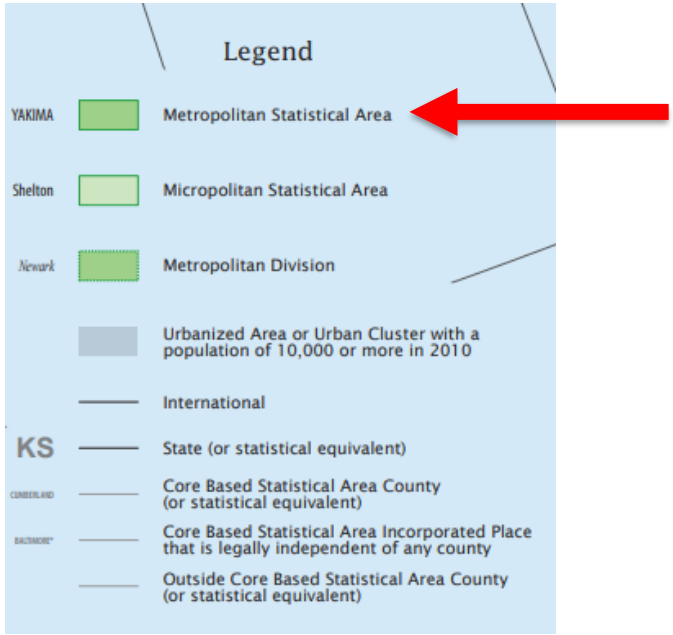
CMS Expands Medicare Telehealth Reimbursement

- **Pre-COVID-19 Requirements for Originating Site**
  - The beneficiary must go to the originating site for the services located in either: (a) a county outside an MSA; or (b) a rural HPSA in a rural census tract
  - Originating Site = physician and practitioner offices; hospitals; CAHs; RHCs; FQHCs; hospital- or CAH-based Renal Dialysis Centers; SNFs; CMHCs; Renal Dialysis Facilities; homes of home-based ESRD patients; mobile stroke units
  - Facility Fee

CMS Expands Medicare Telehealth Reimbursement

- U.S. Office of Management and Budget – Metropolitan Statistical Areas





https://www2.census.gov/geo/maps/metroarea/us_wall/Sep2018/CBSA_Wall Map_Sep2018.pdf?#

CMS Expands Medicare Telehealth Reimbursement

- **What has changed:**
  - Originating Site requirement waived
  - Patient can be seen from any location (including home); need not be located at an Originating Site
  - If patient is not seen at a rural Originating Site, no facility fee is paid (practitioner can receive increased reimbursement)
  - Effective March 6, 2020
- Goal is to minimize community spread of COVID-19

CMS Expands Medicare Telehealth Reimbursement

- **Pre-COVID-19 Requirements for Distant Site Practitioner**
  - Eligible practitioners:
    - Physicians
    - NPs
    - PAs
    - Nurse-midwives
    - Clinical nurse specialists
    - CRNAs
    - Clinical psychologists and clinical social workers (certain CPT codes excluded)
    - Registered dieticians/nutrition professionals

CMS Expands Medicare Telehealth Reimbursement

- **What has changed:**
  - Under CARES Act, FQHCs/RHCs may serve as distant site during the Public Health Emergency
  - CMS has waived the requirement that a practitioner be licensed in the State in which he or she is practicing, if the practitioner:

    (1) is enrolled in Medicare program;

    (2) possesses a valid license to practice in the State which relates to his or her Medicare enrollment;

    (3) is furnishing services–whether in person or via telehealth–in a State in which the emergency is occurring in order to contribute to relief efforts in his or her professional capacity; and

    (4) is not affirmatively excluded from practice in the State or any other State that is part of the waiver emergency area.

CMS Expands Medicare Telehealth Reimbursement

- **What has not changed:**
  - If practitioners furnish Medicare telehealth services from their homes, they must update their Medicare enrollments with their home locations. If practitioners reassign their benefits to clinic/group practices, the clinic/group practices must update their Medicare enrollments with the practitioners' home locations.
- Each MAC has set up a COVID-19 Medicare Provider Enrollment Relief Hotline
  - Wisconsin Physician Services

    1-844-209-2567 (7:00 am – 4:00 pm CT)

  https://www.cms.gov/files/document/provider-enrollment-relief-faqs-covid-19.pdf

CMS Expands Medicare Telehealth Reimbursement

- **Use of Telephone (Audio-Only) – What's Changed**
  - CARES Act removed requirement under CPRSAA that if telehealth is delivered via telephone, it "has audio and video capabilities that are used for two-way, real-time interactive communication."
  - However, 42 C.F.R. § 410.78 requires use of "audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner. **Telephones**, facsimile machines, and electronic mail systems **do not meet the definition of an interactive telecommunications system**."
  - During the Public Health Emergency, services may be provided by telephone (CPT codes 98966-98968; 99441-99443)

    https://www.cms.gov/files/document/covid-final-ifc.pdf

    https://www.cms.gov/files/document/covid-19-physicians-and-practitioners.pdf

CMS Expands Medicare Telehealth Reimbursement

Type of Service	Description of Communication	HCPCS/CPT Codes	Patient Relationship with Provider
Medicare Telehealth Visits	Health care professional must use an interactive audio and video telecommunications system that permits real-time communication between the professional and the beneficiary, **except for CPT codes 98966 -98968; 99441-99443, which may be provided by telephone.**	Those listed in the current Medicare Physician Fee Schedule. **Additional CPT codes listed in https://www.cms.gov/files/document/covid-final-ifc.pdf**	New Patients *or* Established Patients
Virtual Check-In	A brief (5-10 minute) patient-initiated check in with a health care professional via telephone or other telecommunications device to decide whether an office visit or other service is needed. A remote evaluation of recorded video and/or images submitted by a patient.	HCPCS codes G2010 and G2012	**New Patients** ***or*** Established Patients
E-Visits	A communication between a patient and a healthcare professional through an online patient portal.	CPT codes: 99421, 99422, 99423 HCPCS codes: G2061, G2062, G2063	**New Patients** ***or*** Established Patients

CMS Expands Medicare Telehealth Reimbursement

- Additional regulatory flexibility regarding in-person visits for:
  - ESRD
  - Home dialysis
  - SNF
  - Inpatient rehabilitation
  - Hospice
  - Home health
- Certain required direct physician supervision of non-physician practitioners may be done by telehealth
- CMS will reimburse for therapy codes, even though PT, OT, SLP not authorized distant providers

  https://www.cms.gov/files/document/covid-final-ifc.pdf

Implication for Medicare Advantage

- **What has not Changed:**
  - MA plans are required to offer same telehealth services as FFS
  - Are permitted (but not required) to cover additional telehealth services; many do as a way to lower costs
- **What has Changed:**
  - CMS has authorized MA plans to waive beneficiary cost sharing during the Public Health Emergency
  - CMS is exercising enforcement authority for MA plans that wish to provide additional telehealth services during the Public Health Emergency beyond what has been approved by CMS
  - https://www.cms.gov/files/document/hpms-memo-covid-information-plans.pdf

MDHHS Medicaid Telehealth Policy Changes

- Federal Medicare guidance
  - States have broad flexibility to cover telehealth through Medicaid, including the methods of communication (such as telephonic, video technology commonly available on smart phones and other devices) to use. … No federal approval is needed for state Medicaid programs to reimburse providers for telehealth services in the same manner or at the same rate that states pay for face-to-face services. A SPA would be necessary to accommodate any revisions to payment methodologies to account for telehealth costs.

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

MDHHS Medicaid Telehealth Policy Changes

- Medicaid uses the more restrictive (compared to scope of practice) definition of “telemedicine” found in Michigan’s telemedicine parity statute (MCL 500.3476):
  - “Telemedicine” means the use of an electronic media to link patients with health care professionals in different locations. To be considered telemedicine under this section, the health care professional must be able to examine the patient via a real-time, interactive audio or video, or both, telecommunications system and the patient must be able to interact with the off-site health care professional at the time the services are provided

MDHHS Medicaid Telehealth Policy Changes

- Originating Site and Distant Site requirements

  See: https://www.michigan.gov/documents/mdhhs/MSA_20-09_683712_7.pdf

- Telemedicine fee schedule

  See:https://content.govdelivery.com/attachments/MIDHHS/2020/03/20/file_attachments/1407135/MSA%2020-13-CORRECTED.pdf

MDHHS Medicaid Telehealth Policy Changes

- **What has Changed:**
  - MDHHS now allows Medicaid beneficiaries to receive telemedicine services, and practitioners to provide those services, from their respective homes, or from other locations deemed appropriate by the practitioner

    https://www.michigan.gov/documents/mdhhs/MSA_20-09_683712_7.pdf
  - MDHHS will reimburse all codes it its telemedicine database to be delivered via telephonic (audio) only

    https://content.govdelivery.com/attachments/MIDHHS/2020/03/20/file_attachments/1407135/MSA%2020-13-CORRECTED.pdf

Select Fraud and Abuse Issues

- OIG Guidance Regarding Medicare Cost-Sharing Obligations
  https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf
- Under Assignment rules still apply
- CMS Stark Law waiver - hospitals and other health care providers can pay above or below fair market value to rent equipment or receive services from physicians (or vice versa)
  https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf

Commercial Payor Response

- Telehealth parity since 2012
- Many payors had already implemented broader telehealth reimbursement
- Payors have responded to COVID-19, including waiving copays for telehealth visits and allowing services provided via telephone typically billed at lower telehealth rate to be billed as equivalent to face-to-face visits
- Varies between payors and state-by-state

Future of Telehealth Reimbursement Landscape

- COVID-19 as a disrupter of health care delivery regarding telehealth
- Rapid implementation of telehealth infrastructure
- Overcoming barriers to implementation, including operational issues, patient comfort with technology
- Opportunities in post-acute care, behavioral health
- Opportunities for expansion of direct to consumer services

Future of Telehealth Reimbursement Landscape

- How will state legislatures/licensing authorities respond?
- How will payors respond?
  - Medicare, Medicaid
    - Congressional action
    - Generally slow regulatory process
  - Commercial Payors

PRIVACY

OCR Enforcement Discretion - Telehealth

- March 17, 2020 & March 20, 2020 – OCR issued guidance indicating that it will exercise enforcement discretion and waive penalties for entities providing services through “everyday communication technologies”
- Applies to all **Provider** Covered Entities who provide telehealth services during the COVID -19 public health emergency. Enforcement discretion does not apply to other types of Covered Entities, such as insurance companies, health plans and clearinghouses
- All services considered by the Provider to be appropriate for telehealth are covered by this guidance
- Applies to violations (relating to telehealth services) of privacy, security and breach notification rules
- Does not waive any other HIPAA privacy or security requirements

OCR Enforcement Discretion - Telehealth

- OCR relies on the definition of “telehealth” used by the Health Resources and Service Administration of DHHS
  - Means “the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care, patient and professional health-related education, and public health and health administration”
- For purposes of the OCR guidance, telehealth may be provided through audio, text messaging, or video conferencing

https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

https://www.hhs.gov/sites/default/files/telehealth-faqs-508.pd

OCR Enforcement Discretion – Telehealth (cont'd)

- Enforcement discretion only applies for violations that occur during the **good faith** provision of telehealth services during the COVID-19 public health emergency.
- OCR provided examples of what would be considered **bad faith** use of telehealth, including:
  - Conducting or furthering a criminal act, such as fraud, identity theft, and intentional invasion of privacy;
  - Any use or disclosure of PHI prohibited by HIPAA, sale of the data, or use of the data for marketing (without an authorization)
  - Any use of telehealth that violates state licensing laws or professional ethical standards and that results in disciplinary actions related to the telehealth services; or
  - Use of any form of remote communication identified by OCR as unacceptable, such as Facebook Live, Twitch, or a chat room like Slack.

OCR Enforcement Discretion – Telehealth (cont'd)

- OCR recommends that telehealth be conducted in private settings with telehealth used in public settings only in exigent circumstances.
- Providers should continue to:
  - Implement all HIPAA safeguards and take whatever steps are reasonable to keep the telehealth sessions confidential.
  - Comply with all privacy rule requirements
    - Minimum necessary
    - Obtain authorizations were appropriate
    - Provide new patients with Notice of Privacy Practices.
- Providers providing services through telehealth must continue to comply with state licensure and scope of practice laws

OCR Enforcement Discretion - BAs

- Current regulation (42 CFR 502(e)(2)) permits Business Associates to use or disclose PHI for public health and health oversight purposes only if that use or disclosure is expressly permitted by the Business Associate Agreement or if it is required by law
- OCR issued proposed regulations to provide that OCR will exercise enforcement discretion for Covered Entities and Business Associates who use and disclose PHI for public health and health oversight purposes provided that the use or disclosure is in **good faith**
  - Such as:
    - To CDC to prevent or combat spread; or
    - To CMS for oversight and assistance
- Does not address breach of contract or violation of other state or federal laws.

https://www.hhs.gov/sites/default/files/notification-enforcement-discretion-hipaa.pdf

Disclosures to First Responders

- March 24, 2020 - OCR issued guidance describing the circumstances under which Covered Entities may disclose PHI about an individual who has been infected or exposed to COVID-19 to law enforcement, paramedics, other first responders and public health authorities
- Covered Entities may make such disclosures in the following circumstances:
  - When necessary for treatment;
  - When required by law;
  - When first responders may be at risk of infection; or
  - When necessary to lessen a serious threat or imminent threat to public
- Covered Entities are expected to provide only the minimum necessary information to first responders, except in cases of treatment or where required by law

https://www.hhs.gov/sites/default/files/covid-19-hipaa-and-first-responders-508.pdf

Disclosures Related to COVID-19 Testing

- April 9, 2020 - OCR issued guidance indicating that it will exercise enforcement discretion and waive penalties for Covered Entities and Business Associates in connection with **good faith** operation of test sites for COVD-19
- Effective retroactive to March 13, 2020
- Applies only to **Provider** Covered Entities who provide specimen collection or testing services for COVID-19
- Does not apply to other types of Covered Entities, such as insurance companies, health plans and clearinghouses
- Includes all activities that support the collection of specimens for COVID-19 testing
  - In retail lab or pharmacy- only applies to testing site
  - Breach of EHR – still a breach even if test PHI in EHR

Disclosures Related to COVID-19 Testing (cont'd)

- Must continue to implement reasonable safeguards
  - Disclose only minimum necessary, except treatment
  - Set up canopies or opaque screens
  - Control foot and car traffic
  - Establish buffer zone – prevent media and public observation
  - Implement security for recording and transmitting PHI
  - Post Notice of Privacy Practices
- No penalties for violation of privacy, security and breach notification rules.

Questions, Slides, HRCI

- Email questions to kkudner@dykema.com, kreed@dykema.com or smooradian@dykema.com
- Slides and webinar recording provided after program

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