

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Health Data and Analytics
Division of Telehealth Services
(Amended After Comments)

900 KAR 12:005. Telehealth terminology and requirements.

RELATES TO: KRS 205.510, 205.559, 205.5591, 211.332(2)-(5), 304.17A-005(23), 304.17A-138, 304.40-320, 311.5975, 31 U.S.C. § 3729-3733, 42 U.S.C. § 1320a-7b(b), 42 U.S.C. secs. 1320d to 1320d-9, 42 U.S.C. § 1395nn

STATUTORY AUTHORITY: KRS 194A.105, 211.334(1)(d), 211.336(3)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 211.334 and 211.336 require the secretary of the Cabinet for Health and Family Services to promulgate administrative regulations necessary under applicable state laws to establish a telehealth terminology glossary to provide standard definitions for all health care providers who deliver health care services via telehealth, all state agencies authorized or required to promulgate administrative regulations relating to telehealth, and all payors; establish minimum requirements for the proper use and security of telehealth including requirements for confidentiality and data integrity, privacy, and security, informed consent, privileging and credentialing, reimbursement, and technology; and establish minimum requirements to prevent waste, fraud, and abuse related to telehealth.

Section 1. Definitions. (1) "Department" means Department for Medicaid Services.

(2) "Division" means Division of Telehealth Services.

(3) **"Health care provider" is defined by KRS 304.17A-005(23), unless the provider or service is otherwise regulated by KRS 205.8451(7).**

~~(4)~~~~(3)~~ "Health care service" is defined by KRS 211.332(2).

~~(5)~~~~(4)~~ "Professional licensure board" is defined by KRS 211.332(3).

~~(6)~~~~(5)~~ "State agency authorized or required to promulgate administrative regulations relating to telehealth" is defined by KRS 211.332(4).

~~(7)~~~~(6)~~ "Telehealth" or "digital health" is defined by KRS 211.332(5).

Section 2. Compliance. (1) Health care providers performing a telehealth or digital health service shall:

(a) Maintain confidentiality of patient medical information in accordance with KRS 311.5975;

(b) Maintain patient privacy and security in accordance with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. secs. 1320d to 1320d-9, unless waived by the applicable federal authority;

(c) Obtain patient informed consent in accordance with KRS 311.5975 and KRS 304.40-320;

(d) Secure credentialing if required by a third party or insurer or other payor;

(e) **Establish guidelines to contact, refer, and obtain treatment for a patient who needs emergent or higher level-of-care services provided by a hospital or other facility** ~~[Obtain privileges by hospitals or facilities to admit and treat patients];~~

(f)1. Utilize the appropriate current procedural terminology (CPT) or health care common procedure coding (HCPCS) code and place of service (POS) code "02" to secure reimbursement for a professional telehealth service; or

2. Utilize appropriate telehealth service code, if a CPT or HCPCS code is not available or not used for that service, according to customary practices for that health care profession, in-

cluding the use of any telehealth modifiers or alternate codes;

(g) Utilize non-public facing technology products that are HIPAA compliant;

(h) As appropriate for the service, provider, and recipient, utilize the following modalities of communication delivered over a secure communications connection that complies with the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. secs. 1320d to 1320d-9:

1. Live or real-time audio and video synchronous telehealth technology;

2. Asynchronous store-and-forward telehealth technology;

3. Remote patient monitoring using wireless devices, wearable sensors, or implanted health monitors;

4. Audio-only telecommunications systems; or

5. Clinical text chat technology when:

a. Utilized within a secure, HIPAA compliant application or electronic health record system;

and

b. Meeting:

(i) The scope of the provider's professional licensure; and

(ii) The scope of practice of the provider; and

(i) Comply with the following federal laws to prevent waste, fraud, and abuse relating to telehealth:

1. False Claims Act, 31 U.S.C. § 3729-3733;

2. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and

3. Physician Self-Referral, Section 1877 of the Social Security Act (42 U.S.C. § 1395nn).

Section 3. Incorporation by Reference.

(1) "Telehealth Terminology Glossary", July 2021, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Telehealth Services, 275 East Main Street 4WE, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m., or from its Web site at <https://telehealth.ky.gov>.

ANDREW BLEDSOE, Deputy Executive Director

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 4, 2021

FILED WITH LRC: November 12, 2021 at 8:00 a.m.

CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Kim Minter or Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes a telehealth terminology glossary and establishes requirements to prevent waste, fraud, and abuse.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to establish a telehealth glossary to be utilized by state agencies when promulgating telehealth administrative regulations, and by health care providers and payors to understand telehealth in the delivery of health care services, and establishes requirements to prevent waste,

fraud, and abuse in KRS 211.334 and 211.336 and required by HB 140, Ky. Acts Ch. 67, from the 2021 Regular Session.

(c) How this administrative regulation conforms to the content of the authorizing statutes. The administrative regulation conforms to the content of the authorizing statutes by establishing a telehealth glossary and requirements for use.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effective administration of the statutes by establishing a telehealth glossary and requirements. KRS 211.334(1) authorizes the cabinet, in consultation with the Division of Telehealth Services within the Office of Health Data and Analytics, to provide guidance and direction to providers delivering health care services using telehealth or digital health; and to promote access to health care services provided via telehealth or digital health.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.

(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.

(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: This increase will impact those payors, providers, members, and recipients who are regulated by state government. In the early part of the pandemic, telehealth utilization increased and was about 78 times higher than previous levels. Over the course of the COVID-19 pandemic, telehealth usage appears to have stabilized at levels that are about 38 times higher than pre-pandemic telehealth utilization. The Cabinet for Health and Family Services anticipates that increased telehealth utilization will be an ongoing feature of the healthcare system.

This administrative regulation is being further amended in response to comment to add a definition for health care provider, and clarify the responsibility of health care providers providing telehealth in addressing how to secure higher level of care services – including emergent services – for patients.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in questions (3) will have to take to comply with this administrative regulation or amendment: All health care providers who deliver health care services via telehealth, all state agencies authorized or required to promulgate administrative regulations relating to telehealth, and all payors should utilize the glossary for consistency when referencing telehealth terminology.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the identities identified in question (3): No cost is imposed on the entities regulated by this administrative regulation.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Telehealth Terminology Glossary will assist providers, consumers, patients, and stakeholders in understanding telehealth within the health care system as well as standardizing

telehealth language across all state agencies who promulgate telehealth legislation.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: The department anticipates that it will incur no additional expenses in the implementation of this administrative regulation in the first year of operation.

(b) On a continuing basis: The department anticipates that it will incur no additional expenses in implementing this administrative regulation on a continuing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Federal Centers for Medicare and Medicaid Services (CMS) funding, state restricted funding, and MCO capitation fees.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new or by the change, if it is an amendment: No increase in fees or funding is anticipated with implementing this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increased any fees. This administrative regulation neither establishes nor increases any fees.

(9) TIERING: Is tiering applied? Tiering was not applied as telehealth requirements are applied equally to all affected.

FEDERAL MANDATE ANALYSIS COMPARISON

1. Federal statute or regulation constituting the federal mandate. 31 U.S.C. § 3729-3733, 42 U.S.C. § 1320a-7b(b), 42 U.S.C. secs. 1320d to 1320d-9, 42 U.S.C. § 1395nn

2. State compliance standards. Meeting federal standards by complying with privacy, security, waste, fraud, and abuse requirements.

3. Minimum or uniform standards contained in the federal mandate. Meeting federal standards by complying with privacy, security, waste, fraud and abuse requirements.

4. Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate? No

5. Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements. Not applicable.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

1. What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department for Medicaid Services (DMS) and all state agencies authorized or required to promulgate administrative regulations relating to telehealth, and all payors.

2. Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 194A.105, 205.510, 205.559, 205.5591, 211.332(2)-(5), 211.334(1)(d), 211.336(3), 304.17A-005(23), 304.17A-138, 304.40-320, 311.5975, 31 U.S.C. § 3729-3733, 42 U.S.C. § 1320a-7b(b), 42 U.S.C. secs. 1320d to 1320d-9, 42 U.S.C. § 1395nn

3. Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation is not expected to generate revenue for state or local government in

the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation is not expected to generate revenue for state or local government in subsequent years.

(c) How much will it cost to administer this program for the first year? The department anticipates no additional costs in administering this administrative regulation in the first year.

(d) How much will it cost to administer this program for subsequent years? The department anticipates no additional costs in administering this administrative regulation in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: