

Jason Kander

Secretary of State
Administrative Rules Division

RULE TRANSMITTAL

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SEP 21 2016

SECRETARY OF STATE
ADMINISTRATIVE RULES

Rule Number 13 CSR 65-3.050

COPY

Use a "SEPARATE" rule transmittal sheet for EACH individual rulemaking.

Name of person to call with questions about this rule:

Content Sarah Madden Phone 522-8368 FAX 522-6092

Email address Sarah.Madden@dss.mo.gov

Data Entry Debbie Lindquist Phone 526-0414 FAX 522-6092

Email address Deborah.Lindquist@dss.mo.gov

Interagency mailing address 221 W High, Broadway Bldg., Jefferson City, Mo 65109

TYPE OF RULEMAKING ACTION TO BE TAKEN

- Emergency rulemaking, include effective date
 Proposed Rulemaking
 Withdrawal Rule Action Notice In Addition Rule Under Consideration
 Request for Non-Substantive Change
 Statement of Actual Cost
 Order of Rulemaking

Effective Date for the Order _____

Statutory 30 days OR Specific date _____

Does the Order of Rulemaking contain changes to the rule text? NO

YES—LIST THE SECTIONS WITH CHANGES, including any deleted rule text:

Small Business Regulatory
Fairness Board (DED) Stamp

JCAR Stamp

JOINT COMMITTEE ON

SEP 21 2016

ADMINISTRATIVE RULES

Missouri Department of
SOCIAL SERVICES

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JEREMIAH W. (JAY) NIXON, GOVERNOR • BRIAN KINKADE, DIRECTOR

MISSOURI MEDICAID AUDIT & COMPLIANCE UNIT

JESSICA DRESNER, M. ED. DIVISION DIRECTOR

P.O. BOX 6500, JEFFERSON STATE OFFICE BUILDING, JEFFERSON CITY, MO 65102

www.dss.mo.gov • 573-751-3399 • 573-526-2054 fax

September 21, 2016

Jason Kander
Secretary of State
Administrative Rules Division
600 West Main Street
Jefferson City, Missouri 65101

Re: 13 CSR 65-3.050 – Electronic Signatures for MO HealthNet Program

Dear Secretary Kander,

CERTIFICATION OF ADMINISTRATIVE RULE

I do hereby certify that the attached is an accurate and complete copy of the proposed rulemaking lawfully submitted by Missouri Medicaid Audit Compliance Unit, Department of Social Services.

The Missouri Medicaid Audit Compliance Unit, Department of Social Services has determined and hereby certifies that this proposed rulemaking will not have an economic impact on small businesses. The Missouri Medicaid Audit Compliance further certifies that it has conducted an analysis of whether or not there has been a taking of real property pursuant to section 536.017, RSMo 2000, that the proposed rulemaking does not constitute a taking of real property under relevant state and federal law, and the proposed rulemaking conforms to the requirements of 1.310. RSMo Supp. 2009, regarding user fees.

The Missouri Medicaid Audit Compliance, Department of Social Services has determined and hereby also certifies that this proposed rulemaking complies with the small business requirements of 1.310, RSMo, in that it does not have an adverse impact on small businesses consisting of fewer than fifty full or part-time employees or it is necessary to protect the life, health, or safety of the public, or that this rulemaking complies with 1.310, RSMo, by exempting any small business consisting of fewer than fifty full or part-time employees from its coverage, by implementing a federal mandate, or by implementing a federal program administered by the state or an act of the general assembly.

Statutory Authority: Statutory Authority: sections 660.017 and 208.159, RSMo 2000

If there are any questions regarding the content of this proposed rulemaking, please contact:

Sarah G. Madden
221 West High Street, Room 230
Jefferson City, MO 65102
572-526-0414
Sarah.Madden@dss.mo.gov

Sincerely,



Jessica Dresner, M. Ed.
Director, Missouri Medicaid Audit & Compliance

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AFFIDAVIT

PUBLIC COST

State of MISSOURI)
) ss.
County of COLE)

I, Jessica Dresner, Director of the Missouri Medicaid Audit Compliance Unit, Department of Social Services, first being duly sworn, on my oath, state that it is my opinion that the cost of the proposed rule, 13 CSR 65-3.050 is less than five hundred dollars (\$500) in the aggregate to this agency, any other agency of state government or any political subdivision thereof.


Jessica Dresner, Director
Missouri Medicaid Audit Compliance

Subscribed and sworn to before me this 21st day of September 2016. I am commissioned as a Notary Public within the County of Cole, State of Missouri, and my commission expires October 22, 2017.


Notary Public

DEBORAH S. LINDQUIST
Notary Public - Notary Seal
STATE OF MISSOURI
County of Cole
My Commission Expires 10/22/2017
Commission # 13545625

Title 13—DEPARTMENT OF SOCIAL SERVICES
Division 65—Missouri Medicaid Audit and Compliance Unit
Chapter 3 Providers and Participants—General Provider and Participant Policies

RECEIVED

PROPOSED RULE

SEP 21 2016

13 CSR 65-3.050 Electronic Signatures for Mo HealthNet Program

SECRETARY OF STATE
ADMINISTRATIVE RULES

PURPOSE: This rule establishes the basis on which Health Care Providers and participants under Missouri Medicaid Title XIX Programs may utilize electronic signatures when validating services rendered and received.

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(1) As used in this rule, the following terms shall mean:

(A) **“Electronic Health Record”** means an electronic record of health-related information on an individual that may include patient demographic and clinical health information, such as medical histories and problem lists; and has the capacity to provide clinical decision support; to support physician order entry; to capture and query information relevant to health care quality; and to exchange electronic health information with, and integrate such information from other sources (as defined by ARRA).

(B) **“Electronic Service Record”** means an electronic record of information on an individual that is required as a component of the service provision including, but not limited to, defined evidence of service, log/observation notes, data collection, periodic reporting, and notification documentation. Information required as a component of service provision may be defined within the State of Missouri Waiver Manuals, the Code of State Regulations, State Statute, contracts with individual service providers, and other related documentation utilized to regulate the service.

(C) **“Electronic Signature”** means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual with the intent to be the legally binding equivalent of the individual’s handwritten signature. An electronic signature shall not include biometrics such as fingerprinting; however, MMAC or a provider may allow the use of biometrics, retinal-iris image scan, facial image scan, voice verification or palm or fingerprint verification and other related technology as part of the electronic signature verification. These biometrics features shall comply with: The Registry of USG Recommended Biometric Standards (Registry) supplements the NSTC Policy for Enabling the Development, Adoption and Use of Biometric Standards.

(D) **“Participant”** means any individual that is a current participant under the Missouri Medicaid Title XIX program.

(E) **“Provider”** means any health care provider currently participating and providing services under Title XIX and under Title XXI of the federal Social Security Act.

(F) **“Signature Stamp”** officially deemed impermissible to use for medical review purposes (see CMS Pub 100-08 Transmittal 327).

(2) This rule applies to any electronic health record, electronic service record or electronic signature, as defined in 13 CSR 65-2.010, which is created, generated, sent, communicated, received, or stored involving a provider or participant.

(3) If a law or regulation requires a record to be in writing, an electronic health record shall satisfy such law for MO HealthNet purposes. If a law or regulation requires a signature to be in writing, an electronic signature shall satisfy such law for MO HealthNet purposes.

(4) Both the provider and the participant must consent to conduct business electronically. Nothing in this regulation requires parties to conduct business electronically.

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(5) If a provider and a participant agree to conduct business electronically, then the following requirements apply to the provider:

(A) Only employees or agents designated by the provider may make entries in the participant's electronic health record or electronic service record;

(B) All entries in the participant's electronic health record or electronic service record must be authenticated with a method established to identify the author. The identification may include computer keys/codes, voice authentication systems that utilize a personal identification number (PIN) and voice authentication or other codes;

(C) Providers shall have a process in place to deactivate and disable an employee's or an agent's access to medical records upon suspension or termination of employment or agency relationship;

(D) Provider's electronic health records and/or electronic service record system shall maintain an activity tracking system to monitor and record user activity for all documents in a participant's record that are viewed, created, updated or modified. The tracking system must record the following for each activity; and:

1. User log-in and log-out dates and times;
2. User identification;
3. An IP address; and
4. Dates and times when records are viewed, created, updated or modified.

(E) When computer key/code(s), voice authentication systems, or other codes are used, a provider shall have each authorized employee or agent read and sign an attestation documenting that the chosen method is under the sole control of the employee or agent using it. The provider must further demonstrate that a list of computer key/code(s), voice authentication systems, or other codes can be verified and all adequate safeguards are maintained to protect against improper or unauthorized use of computer key/code(s), or other codes for electronic signatures.

(6) During system access of electronic health or service records, the provider and their employees or agents shall review and agree to a statement, with electronic health records and/or health service records for MO HealthNet participants that contain the following:

(A) The documentation made and information provided in each participant's record accurately reflects the services provided, diagnosis made, treatments provided, and information recorded during that session;

(B) The electronic health record and/or health service record accurately reflects the provider's or its employee's or agent's role, relationship, position and intent as indicated by his or her name, title and capacity for the participant's record;

(C) The information provided is true, accurate, and complete to the best of the individual's knowledge;

(D) The individual understands that any falsification, omission, or concealment of material facts may subject the individual to administrative, civil, or criminal liability; and

(E) The individual understands that an electronic signature has the same legal effect and can be enforced in the same way as a written signature.

(7) Providers' and participants' electronic signatures on electronic health records and electronic service records maintained by the provider shall contain information associated with the signature that clearly indicates all of the following:

(A) The printed complete name of the signer;

(B) If applicable, the professional title of the electronic signer, such as M.D., R.N., P.A., etc.

(C) The date and time the signature was executed; and

(D) The meaning associated with the signature, such as review, approval, responsibility, submitted by, entered by, updated by, created by, read by, viewed by or similar authorship. The meaning for applying an electronic signature to a certain record type can be defined by the type of record as long as such meaning is clarified in procedure and is understood by the electronic signer.

(8) A provider's process for using electronic signatures of the provider or its employees or agents shall comply with the following requirements:

(A) Each electronic signature and affiliated initial system shall be unique to one individual and shall not be reused by, or reassigned to, anyone else that is employed by, consultant to, or an agent of the provider.

(B) Before a provider establishes, assigns, certifies, or otherwise approves an individual's electronic signature, controlled system access, or any element of such electronic signature, the provider shall verify the identity of the individual.

(C) Before electronically signing, providers and their employees and agents shall certify to the Department that the electronic signatures in their system are intended to be the legally binding equivalent of traditional handwritten signatures as they pertain to the MO HealthNet program.

(D) Upon the Department's request, providers and their employees and agents shall provide additional certification that a specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

(E) The electronic signatures of the provider and its employees and agents shall:

1. Include at least two distinct identification components, such as an identification code and password;

2. Be used only by their genuine owners;

3. Not constitute a signature stamp; and

4. Be administered and executed to ensure that attempted use of a provider's and or its employees' or agents' electronic signatures by anyone other than its genuine owner requires collaboration of two or more individuals.

(9) A provider's process for using electronic signatures of MO HealthNet participants shall comply with the following requirements:

(A) A participant's electronic signature shall be verified with photo identification by the attending provider or its employee or agent prior to accepting the participant's signature;

(B) A participant's electronic signature must be available to review by MMAC;

(C) The participant shall execute or attest to the following statement, or a similar statement with comparable intent:

"I, [Participant Full Name] , understand that an electronic signature has the same legal effect and can be enforced in the same way as a written signature"

(D) The provider shall be responsible for ensuring that the details of the service as defined by the documented evidence of that service, such as the date, time, and services provided shall be clearly identified in connection with the electronic signature.

(10) When a change or error in an electronic health record occurs:

(A) All original records must be maintained once an electronic signature has been applied attesting to the author's ownership of the wording of the record

(B) Any edits of the records must be saved as an update to the original record with date, time and information by author including his or her name and title, if applicable.

(C) The edits are to be credited to the new author and not the original author.

(11) Providers shall implement a written internal organizational policy that:

(A) Addresses the issue of protection for the use of electronic signatures by anyone other than that to whom the electronic signer intended;

(B) Includes the following three elements:

1. Nonrepudiation—assurance that the signer cannot deny signing the document in the future;

2. Each entry shall be time and date stamped with the author's name and title, and identify the action of the entry;

3. The User will be responsible for each entry as the original author;

(C) Requires the provider to retain electronic health records for a minimum period of ten (10) years, unless the records are the subject of an audit or litigation. Records that are the subject of an audit or litigation shall be maintained until the conclusion of the audit or litigation. The documents also shall be retained for a longer period of time at the request of MMAC, if a written demand to keep such records is delivered to the provider;

(D) Ensures that all electronic signatures are accurate, legible and accessible;

(E) Requires the provider to produce a copy of the services rendered for participants to review prior to obtaining participants' electronic signatures verifying receipt of the prescribed services; and

(F) Recognizes the following:

1. The definition of electronic signature;

2. How the Provider's system of electronic signature comports with each of the elements of acceptable use specified above;

3. Acknowledgment that the electronic signature is legally enforceable;

4. Retention of an electronic document with an acceptable electronic signature will satisfy record retention requirements; and

5. Failure to comply with the prescribed requirements may subject an individual to prosecution under all applicable federal and state criminal and civil laws.

AUTHORITY: sections 660.017 and 208.159, RSMo 2000.

PUBLIC COST: This proposed rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the aggregate.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this rule with the Department of Social Services, Jessica Dresner, Director, Missouri Medicaid Audit and Compliance Unit, P.O. Box 6500, 205 Jefferson St., 2nd Floor, Jefferson City, MO 65102. To be considered, comments must be received within thirty (30) days after publication of this notice in the Missouri Register. No public hearing is scheduled.