

TO: Facility Administrator

FROM: Gladys Happi, Project Coordinator
RELI Group

SUBJECT: ESRD QIP Data Validity and Reliability Study – Request for Medical Records

ACTION REQUIRED: Please submit your response by 3/26/2019

The Centers for Medicare & Medicaid Services (CMS) contracted with RELI to assess the accuracy of the Clinical Performance Measures (CPM) data entered into the CROWNWeb. Your dialysis facility has been randomly selected to participate in this effort. Please submit your patient records within 15 days of the receipt of this letter. If you do not respond to this request within 60 days your facility will be identified to CMS.

Similar validation efforts were conducted in early 2014, 2015, and 2016; the findings from those studies have led to changes for reporting of performance measures as well as improved training efforts for facilities. Your participation will give your facility a unique opportunity to have input on any future changes to CMS reporting requirements and will allow you to identify any internal data submission workflow issues.

IMPORTANT: If you do not submit the requested medical records CMS will deduct 10 points from your Total Performance Score (TPS) on the ESRD QIP.

Note: any negative findings from the validation study will not count against your facility.

RELI has randomly selected patients from your facility for medical record review using appropriate identifiers:

- Patient A SSN#
- Patient B SSN#

For each of the identified patients, please securely submit hard copies of the following medical records by **3/26/2019 (see the Secure Submission Requirements section of this document)**. The PRA OMB Control # for this request is OMB-0938-1289. The list of data elements that will be validated is provided below.

System Source	Data Elements to be validated	Description
CROWNWeb	Access Type for Dialysis	Indicates the primary type(s) of access used on the last dialysis treatment date for the patient in the reported Clinical Month
CROWNWeb	Admit Date	Indicates the date the patient started receiving dialysis treatment, transplant or training at current facility.
CROWNWeb	Date of Death	The day on which the patient expires
CROWNWeb	Date of Reported Dialysis Session	Indicates the date of the dialysis session when the Vascular Access type is being reported for the Clinical Month.
CROWNWeb	Date Regular Chronic Dialysis Began	Indicates the first date that the patient started the most recent regularly scheduled course of dialysis treatment for End Stage Renal Disease as prescribed by the Physician.
CROWNWeb	Discharge Date	Indicates the date in which a patient is discharged from a facility.
CROWNWeb	ICH CAHPS Attestation Indicator	Indicates whether or not a facility attested its eligibility status for the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) measure.
CROWNWeb	Initial Certification Date	Indicates the facility's (unique CCN) Original Participation Date within Medicare.
CROWNWeb	Kt/V Hemodialysis	Single Pool Kt/V value for Hemo.
CROWNWeb	Kt/V Hemodialysis Collection Date	Most recent collection date of Single Pool Kt/V value for the reported month ²

Please provide:

- All laboratory reports / results for the months of April, May, and June 2018
- All treatment / flow sheets (full flow sheets, summary is **not** sufficient) for the months of April, May, and June 2018
- All physician orders (must be signed) for the months of April, May, and June 2018
- All physician & nursing progress notes for the months of April, May, and June 2018
- All physician / provider standing protocols for medications and vascular access monitoring
- All patient-specific

documentation of vascular access monitoring results for the months of April, May, and June 2018 (hemodialysis only)

- All vascular access surgical reports and patient-specific vascular access documents (hemodialysis only)
- If any of your selected patients expired during the April through June 2017 timeframe, provide documentation of death such as a death certificate
- Facility (hemodialysis only) policies for:
 - Vascular access physical examination
 - Surveillance of AVG with Doppler ultrasound
 - Arterial pre-pump pressure for AVF / AVG
 - Surveillance of AVG by static venous pressure
 - Surveillance of AVG with Intra-Access Flow Performed
- Additionally, as part of this record request, please complete the enclosed “*Calculation Methods/Processes*” form and submit with the other records. Please refer to the “*Submission Requirements*” section of this document for detailed submission instructions.

Please complete the enclosed patient coversheet for each patient you submit records for, and then use the coversheet to separate the patients’ medical records. One coversheet for each patient record is required. If you are unable to produce a record please indicate so on the coversheet with a brief explanation for the omission.

At the completion of the validation, CMS will receive a report detailing each facility's results. You will receive a report detailing the validation results for your facility to guide data quality efforts at your facility.

If your facility would like to receive reimbursement for records submitted, please include an invoice detailing unit price and quantity of pages copied and shipping costs, along with a copy of your facility’s W-9. RELI is committed to supporting an efficient record retrieval process that minimizes the burden to your dialysis facility. We appreciate your time and cooperation with this project. If you have any questions or concerns regarding this project, please contact myself or Heather Duvall using the information below.

Sincerely,

Gladys Happi, Project Coordinator
ESRDDVSTUDY@RELIGROUPINC.COM

Attachments

Calculation Methods/Processes

Facility Name: _____

Facility CCN: _____

Please circle the appropriate answer to each of the below questions relating to the treatment of patients in your dialysis facility; and return this form to RELI with the medical records requested.

If your facility had hemodialysis patients selected for participation, you are required to answer the following question. Thank you for your time and assistance.

Lab method used for calculation of Kt/V (hemodialysis)?

- a. UKM
- b. Daugirdas II
- e. Other _____

Name/Title of Person Completing Form

Signature

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is **0938-1298 (Expires 02/28/2019)**. The time required to complete this information collection is estimated to average **2.5 hours** per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850. ******CMS Disclosure**** Please do not send applications, claims, payments, medical records or any documents containing sensitive information to the PRA Reports Clearance Office. Please note that any correspondence not pertaining to the information collection burden approved under the associated OMB control number listed on this form will not be reviewed, forwarded, or retained. If you have questions or concerns regarding where to submit your documents, please contact**

1. Gladys N. Happi – Email: gladys.happi@religroupinc.com, Phone: 410-504-4394
2. Khalil Abdul-Rahman – Email: Khalil.Abdul-Rahman@religroupinc.com, Phone: 410-533-2384
3. Raj Saxena – Email: Raj.saxena@religroupinc.com, Phone: 443-873-0227

Secure Submission Requirements

ESRD facilities must ensure confidentiality of patient information when sending protected health information (PHI) and/or personal identifiable information (PII) contained in medical records and CMS forms. **Do not submit any documentation via email.** This may compromise PHI and/or PII and will be reported to the CMS Security Division. Submit all documentation directly to RELI using one of the submission options below. **Documentation should not be submitted to CMS.**

Option 1: PDF Submission

Security Requirements for Sending PDF Copies of Documentation

RELI recommends that documentation is submitted in **PDF format** using a flash drive, CD, or DVD . PDF submission ensures that submissions are received securely and in their entirety.

Flash drives, CDs, or DVDs must be shipped to RELI in tamper-evident packaging with return receipt. Tamper-evident packaging ensures that the package received by RELI reflects any evidence of the contents being compromised.

Preparing PDF Documents on Flash drive, CD or DVD for Submission

1. Ensure that all documentation saved on the device uses the patient coversheets provided with this letter.
2. Include a face sheet inside the packaging that lists your organization's name and contact information.
3. Password-protect the document with the following password: **CCN#_ESRDDVR2018**
Do not include this password in the mailing.
4. Mail your package to:

Attention: Heather Duvall
C/O Healthcare Management Solutions, LLC
1000 Technology Drive, Suite 1310
Fairmont, WV 26554

Option 2: Fax Submission

Security Requirements for Faxing Submissions

Fax submission is permitted if submission via PDF is not feasible. Printers and fax machines must be in a secure location where operation can be observed and where sensitive printed or faxed material can be adequately controlled.

Preparing for Submission via Fax

1. Prepare the fax coversheet. The fax coversheet **must** contain:
 - a. The total number of pages being faxed (including the transmittal sheet). Please be specific and avoid vague wording such as "several" or "a lot" in reference to the number of pages.
 - b. Your facility's contact information (phone number) and a contact name in the event there is a problem with the fax submission.

- c. If you need to separate the document into several faxes please indicate so on the coversheet (ex. Section 1 of 3, Section 2 of 3, etc).
2. Address the fax to: Heather Duvall at **866-779-8488**
3. Observe safeguards: documents containing PHI and/or PII must immediately be cleared from printers and fax machines, paper jams in the fax machines or printer containing private or sensitive data must be immediately removed and secured.
4. Do not leave the fax machine unattended. When fax transmission is complete, remove the original document. Wait for the fax machine to print the transmission confirmation. All fax documents will be received directly into a secure server within the RELI network.

Option 3: Paper Submission

Security Requirements for Sending Hardcopies of Documentation

Documentation must be shipped by **USPS Certified Mail ONLY** in tamper-evident packaging with return receipt. Tamper-evident packaging ensures that the information received by RELI reflects any evidence of the contents being compromised. If a box must be used to mail records, use of tamper-evident tape is acceptable. Your facility will be contacted if packages are received in a compromised state (this may potentially be a breach and reported to CMS).

Preparing Hardcopy Documents for Submission

1. Ensure that all documentation is in the correct order and is clipped together (ex. Paperclip, rubber band) where applicable. **Do Not Use Staples.**
2. Include a face sheet at the beginning of the documentation that includes your organization's name and contact information in the event there is a problem with the submission.
3. Mail your package to:

Attention: Heather Duvall
C/O Healthcare Management Solutions, LLC
1000 Technology Drive, Suite 1310
Fairmont, WV 26554

If you have any questions or concerns regarding your submission, please direct them to Gladys Happi, Project Coordinator via email at ESRDDVRSTUDY@RELIGROUPINC.COM.

Data Elements to be Verified from Source Records

Below is an explanation of what elements will be extracted from medical records provided. Please be sure that the medical records you provide contain these elements when applicable.

- *Laboratory Report* – The Laboratory report must contain the laboratory’s business name, a legend of applied acronyms and abbreviations, the associated patient name, **the date of patient laboratory sampling**, and if applicable the applied method of calculation.

- | | |
|-------------------------------|-----------------------|
| • Kt/V (HD) | • Modality Type |
| • Kt/V HD Collection Date | • Uncorrected Calcium |
| • Kt/V HD Method | • Uncorrected Calcium |
| • Phosphorus | Collection Date |
| • Phosphorous Collection Date | |

- *Treatment/Flow Sheet* – The flow sheet **must be complete (not just a summary)** and contain the date of treatment, the patient’s identifiable information, the patient’s pre/post weight, the patient’s pre/post blood pressure, the initial assessment, prescribed treatment, and administered medications.

- | | | |
|--|--|--|
| • Modality Type | • Treatment Start Date | • Current Access Type/
Access Type for Dialysis |
| • Patient Date of Birth | • Primary Dialysis Setting | • Date of Death |
| • Primary Type of Treatment | • Clinical Depression Screening and Follow-Up Plan Assessment Period | • Treatment Start Date |
| • Number of Dialysis Sessions per Week | • Admit Date | • Primary Dialysis Setting |
| • Pain Assessment and Follow-Up Plan Assessment Period | • Date of Reported Dialysis Session | • ICH CAHPS Attestation Indicator |
| | • Date Regular Chronic Dialysis Began | • Initial Certification Date |
| | • Discharge Date | |

- *Death Certificate* – An official statement, signed by a physician, of the cause, date, and place of a person’s death.

- Date of Death

Patient Coversheet

ESRD Data Validity and Reliability Study

PLEASE SUBMIT ALL REQUESTED PATIENT RECORDS BY 3/26/2019

Facility Name: _____

CCN#: _____

Section I: Patient Information

*Required

*Last Name:		*SSN:	
*First Name:		*DOB:	

Section II: Dates of Service Requested

Dates of Service: April, May, and June 2018*

*Please forward the requested medical records for the above months.

Section III: Missing Medical Records

Please checkmark the box for any missing medical records and provide an explanation for the missing records in the space provided.

- | | |
|---|--|
| <input type="checkbox"/> Physician Orders | <input type="checkbox"/> Treatment/Flow Sheets |
| <input type="checkbox"/> Progress Notes | <input type="checkbox"/> Physician/Provider Standing Protocols |
| <input type="checkbox"/> Laboratory Reports | <input type="checkbox"/> Other Records |

Reason for not including selected medical records:

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