TO: Facility Administrators, Clinical Managers

FROM: XXXXX

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

Thank you for participating in the validation of facility surveillance practices and the Dialysis Event data reported to the National Healthcare Safety Network (NHSN). We appreciate you taking time from your schedule to work with us. Please submit your patient records **within 21 days** of the receipt of this letter.

Based on the line lists provided by your facility, we have identified 10 patients whose medical records will be reviewed to identify the accuracy of dialysis event reporting. The patient medical records selected for review are listed below.

MRN	Patient First Name	Patient Last Name	Patient Date of Birth	Patient Gender

Complete medical records of the patients listed above are requested for the duration of treatment between December 1, 2017 – June 30, 2018.

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. You have a maximum of 60 days from receipt of this letter to submit patient records.

Note: Any negative findings from the validation study <u>will not</u> count against your facility.

Please refer to the Table of Contents on page 2 of this document to find detailed instructions on how to respond to this request. If you have any questions or concerns, please contact me using the information below.

Sincerely,

XXXXX

Table of Contents

1. Form 2728

Each patient's Form 2728 should be placed as the first document in the patient's medical record that is submitted to RELI. This helps us to correctly associate the patient with all related clinical and non-clinical information. Use Form 2728 to separate patient medical records.

If you are unable to provide a patient's medical record, provide a brief explanation of the omission on a separate sheet of paper.

2. 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 using one of the submission options below. **Documentation should not be submitted to CMS.**

Option 1: QualityNet Submission

This is the preferred method. We recommend that documentation is submitted in **PDF format.** Each patient medical record should be prepared as a separate file using the following naming convention:

YourFacilityCCN_PatientFirstName_PatientLastName

Send your patient files via QualityNet to: XXXXX

Option 2: PDF Submission

Security Requirements for Sending PDF Copies of Documentation

We recommend 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 in tamper-evident packaging with return receipt. Tamper-evident packaging ensures that the package received reflects any evidence of the contents being compromised.

Each patient medical record should be prepared as a separate file using the following naming convention:

YourFacilityCCN_PatientFirstName_PatientLastName

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: **YourFacilityCCN_ESRDDVR2018**
   Do not include this password in the mailing.

4. Mail your package to:

   Attention: ESRD QIP DV&R Study

Option 3: 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: ESRD QIP DV&R Study at **XXXXX**

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.

Option 4: 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 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: ESRD QIP DV&R Study

3. Paperwork Reduction Act 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, and 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

XXXXX

4. Invoice Guidance

The Centers for Medicare & Medicaid Services (CMS) contracted with RELI Group to validate positive blood culture "candidate dialysis events" in a sample of dialysis facilities and assess the accuracy of the Dialysis Event data entered into the Center for Disease Control (CDC) NHSN system. Per CMS direction, should you choose to invoice for reimbursement for records submitted, the maximum available reimbursement for the submission of hardcopy documents will be $39.86. No reimbursement will be available for the submission of PDF documents on electronic media or faxed documents. This direction is in accordance with CMS' Data Validation Requirements for the PY 2020 ESRD QIP in the Proposed Rule published at 82 FR 31224, available online at https://www.federalregister.gov/documents/2017/07/05/2017-13908/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis, and the Final Rule published at 82 FR 50790, available online at https://www.federalregister.gov/documents/2017/11/01/2017-23671/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis.

Please be advised that your invoices will be rejected if the amounts billed exceed the maximum amounts reimbursable by CMS, or if the activities invoiced for are not reimbursable by CMS.

If you have any questions, please contact XXXX.