TO: Facility Administrator

FROM: XXXXX

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

The Centers for Medicare & Medicaid Services (CMS) contracted with XXXX to assess the accuracy of Clinical Performance Measures (CPM) data entered into the CROWNWeb system. Your dialysis facility has been randomly selected to participate in this effort. Please submit your patient records **within 21 days** of the receipt of this letter.

Similar validation efforts have been conducted every year since 2014. 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. You have a maximum of 60 days from receipt of this letter to submit patient records.

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

Following the Payment Year (PY) 2019 ESRD QIP Rule, we randomly selected patients from your facility for medical record review. 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.

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

Sincerely,
XXXXXX

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1. Form 2728

Each patient's Form 2728 should be placed as the first document in the patient's medical record that is submitted. 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. Data Elements to be Verified from Source Records

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

- ICH CAHPS Attestation Indicator
- Initial Certification Date

- *Laboratory Reports* – The Laboratory reports for April, May, and June 2018 must contain the laboratory's business name, the associated patient name, **the date of patient laboratory sampling**, and if applicable the applied method of calculation.

    - Kt/V (HD)
    - Kt/V HD Collection Date
    - Kt/V HD Method
    - Phosphorus
    - Phosphorous Collection Date
    - Calcium
    - Calcium Collection Date
    - Modality Type
    - Access Type
    - Session Date
    - Ultrafiltration Pre-Session Weight
    - Ultrafiltration Post-Session Weight
    - Ultrafiltration Session Delivered Minute

- *Treatment/Flow Sheets* – Flow sheets **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.

    - Patient Date of Birth
    - Primary Type of Treatment
    - Number of Dialysis Sessions per Week
    - Pain Assessment and Follow-Up Plan Assessment Period
    - Primary Dialysis Setting
    - Treatment Start Date
    - Clinical Depression Screening and Follow-Up Plan Assessment Period
    - Admit Date
    - Date Regular Chronic Dialysis Began
    - Discharge Date

- *Death Certificate or Form 2746* – An official statement signed by a physician of the cause, date, and place of a person's death.

    - Date of Death

3. 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 all 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: XXXXXX

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

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 by XXX 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

4. 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 0938-1289 (Expires XX /XX/XXXX). 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

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5. Invoice Guidance

The Centers for Medicare & Medicaid Services (CMS) contracted with RELI Group to assess the accuracy of the Clinical Performance Measures (CPM) data entered into the CROWNWeb. 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 $93.00. 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.

All invoices and questions should be sent to XXXXXX