

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE DIALYSIS SERVICES  
PROVIDER COMPLIANCE AUDIT:  
DIALYSIS CLINIC, INC.**

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**September 2022  
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# *Office of Inspector General*

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## Report in Brief

Date: September 2022  
Report No. A-05-20-00010

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
**OFFICE OF INSPECTOR GENERAL**



### Why OIG Did This Audit

Medicare Part B covers dialysis services for beneficiaries with end-stage renal disease (ESRD). Prior OIG reviews identified inappropriate Medicare payments made for ESRD dialysis services that were medically unnecessary, not properly ordered, undocumented, or did not comply with Medicare consolidated billing requirements.

We selected Dialysis Clinic, Inc. (DCI), because it ranked among the highest paid providers of dialysis services in the United States, and Medicare surveyors identified various health and safety issues.

Our objective was to determine whether dialysis services provided by DCI complied with Medicare requirements.

### How OIG Did This Audit

Our audit covered 112,192 claims for dialysis services provided during the audit period (calendar year 2018) for which DCI received Medicare reimbursement totaling \$276,427,841. We reviewed a random sample of 100 claims. We evaluated the services for compliance with Medicare requirements and submitted them to independent medical review.

## Medicare Dialysis Services Provider Compliance Audit: Dialysis Clinic, Inc.

### What OIG Found

DCI claimed reimbursement for dialysis services that did not comply with Medicare requirements for 70 of the 100 sampled claims. Specifically, DCI submitted claims for which: (1) comprehensive assessments or plans of care did not meet Medicare requirements, (2) dialysis treatments were not completed, (3) dialysis services were not documented, (4) beneficiaries' height or weight measurements did not comply with Medicare requirements, and (5) the medical record did not have a monthly progress note by a physician or other qualified professional.

While DCI had established corporate-wide internal controls to monitor and maintain complete, accurate, and accessible medical records at all its facilities, these controls were not always effective in ensuring that DCI's claims for dialysis services complied with Medicare requirements.

We estimated that DCI received unallowable Medicare payments of at least \$14,193,677 for dialysis services that did not comply with Medicare requirements. Many of the errors we identified did not affect DCI's Medicare reimbursement for the services since they were reimbursed on a bundled per treatment basis or related to Medicare conditions for coverage. However, the deficiencies could have a significant impact on the quality of care provided to Medicare beneficiaries and could result in the provision of inappropriate or unnecessary dialysis services.

### What OIG Recommends and DCI Comments

We recommend that DCI refund an estimated \$14,193,677 to the Medicare program. We also made a series of recommendations to strengthen DCI's internal controls to ensure that dialysis services comply with Medicare requirements.

In written comments on our draft report, DCI did not concur with our recommendations but described actions it has taken and plans to take to address some of them. DCI disagreed with our findings and stated the report does not accurately consider the nature of DCI's corporate structure. DCI also stated that our sampling methodology was flawed. After reviewing DCI's comments, we revised our determinations for 15 claims and adjusted our related recommendations accordingly. We maintain that our findings and recommendations, as revised, are valid. We also maintain that our sampling methodology was valid.

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## INTRODUCTION

### WHY WE DID THIS AUDIT

Medicare Part B covers outpatient dialysis services for beneficiaries diagnosed with end-stage renal disease (ESRD). ESRD is a condition in which the kidneys no longer function at the level necessary for day-to-day life. The loss of kidney function in ESRD is usually irreversible and permanent and requires a regular course of dialysis or a kidney transplant. Most individuals with ESRD are eligible for Medicare benefits, regardless of age.

Prior Office of Inspector General (OIG) audits identified inappropriate Medicare payments made for ESRD dialysis services that were medically unnecessary, not properly ordered, undocumented, or did not comply with Medicare consolidated billing requirements.<sup>1</sup>

We reviewed claims for dialysis services submitted for Medicare reimbursement by Dialysis Clinic, Inc. (DCI), because it ranked among the highest paid providers of ESRD services in the United States, and Medicare surveyors<sup>2</sup> identified various safety and quality-of-care issues including, for example, compliance issues associated with the completeness and accuracy in the medical record documentation for plans of care, comprehensive assessments, and flowsheets, among other safety and quality-of-care issues at various DCI facilities during calendar year 2018.

### OBJECTIVE

Our objective was to determine whether dialysis services provided by DCI complied with Medicare requirements.

### BACKGROUND

#### The Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage to people aged 65 or over, people with disabilities, and people with ESRD. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. Medicare Part B provides supplementary medical insurance for medical and other health services, including dialysis services. CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Medicare Part B claims.

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<sup>1</sup> Appendix B contains a list of related Office of Inspector General reports.

<sup>2</sup> State Survey Agencies conduct the CMS Division of Survey and Certification surveys.

## Dialysis Services

Dialysis is the process of removing waste products from the body by diffusion from one fluid compartment to another across a semipermeable membrane. Dialysis procedures can include hemodialysis, peritoneal dialysis, hemofiltration, and ultrafiltration. Of these procedures, two are commonly used for the treatment of ESRD: hemodialysis and peritoneal dialysis.<sup>3</sup>

- Hemodialysis - Blood passes through an artificial kidney machine, and the waste products diffuse across a manmade membrane into a bath solution known as dialysate, after which the cleansed blood is returned to the patient's body. Hemodialysis is accomplished usually in 3- to 5-hour sessions, three times a week.
- Peritoneal dialysis - Waste products pass from the patient's body through the peritoneal membrane into the peritoneal (abdominal) cavity, where the bath solution (dialysate) is introduced and removed periodically. Peritoneal dialysis is particularly suited for patients without caregivers to assist in self-dialysis.

## Medicare Coverage of Dialysis Services

Medicare Part B covers dialysis services, items, supplies, and equipment provided in dialysis facilities<sup>4</sup> to beneficiaries with ESRD.<sup>5</sup> An ESRD facility is an entity that provides outpatient maintenance dialysis services, home dialysis training and support services, or both.<sup>6</sup>

Medicare pays dialysis facilities on a bundled per treatment basis through CMS's ESRD Prospective Payment System (bundled payment). The bundled payment covers all of the resources used in furnishing an outpatient dialysis treatment, including supplies and equipment used to administer dialysis, drugs, biologicals, laboratory tests, training, and support services.<sup>7</sup>

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<sup>3</sup> *Medicare Benefit Policy Manual*, chapter 11, § 10A.

<sup>4</sup> A dialysis facility (we use the term "ESRD facility" in this report) is "an entity that provides outpatient maintenance dialysis services, or home dialysis training and support services, or both. A dialysis facility may be an independent or hospital-based unit (as described in §413.174(b) and (c) of this chapter) that includes a self-care dialysis unit that furnishes only self-dialysis services" (42 CFR § 494.10).

<sup>5</sup> The Act, §§ 1832(a), 1861(s)(2)(F), and 1881(a).

<sup>6</sup> 42 CFR § 494.10.

<sup>7</sup> The Act, § 1881(b)(14)(B); 42 CFR §§ 413.171 and 413.217.



CMS adjusts the bundled payment to account for patient age, height, weight, and comorbidities.<sup>8,9</sup>

To qualify for Medicare payments,<sup>10</sup> dialysis facilities must meet the conditions for coverage (CfC) described in 42 CFR part 494.<sup>11</sup> The CfCs include, but are not limited to, providing each dialysis patient with an individualized comprehensive assessment of his or her needs and developing a written plan of care that specifies the services necessary to address the needs identified in the comprehensive assessment.<sup>12</sup>

Payment for dialysis services will only be made if a physician certifies services that are or were medically required.<sup>13</sup> Dialysis facilities must maintain complete, accurate, and accessible records on all patients and must furnish such information, as appropriate, to determine whether payment is due and the amount of payment.<sup>14</sup>

OIG believes that this audit report constitutes credible information of potential overpayments. Upon receiving credible information of these potential overpayments, providers must exercise reasonable diligence to identify overpayments (i.e., determine receipt of and quantify any overpayments) during a 6-year lookback period. Providers must report and return any identified overpayments by the later of (1) 60 days after identifying those overpayments or (2) the date that any corresponding cost report is due (if applicable). This is known as the 60-day rule.<sup>15</sup>

The 6-year lookback period is not limited by OIG's audit period or restrictions on the Government's ability to reopen claims or cost reports. To report and return overpayments under the 60-day rule, providers can request the reopening of initial

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<sup>8</sup> 42 CFR § 413.235.

<sup>9</sup> Comorbidities are patient-specific conditions that are secondary to the patient's principal diagnosis that necessitates dialysis, yet have a direct effect on dialysis.

<sup>10</sup> 42 CFR § 413.210(a).

<sup>11</sup> These standards focus on the patient and the care provided and are the foundation for ensuring quality care is provided and the health and safety of Medicare beneficiaries is protected. Dialysis facilities that do not comply with CfCs could be subject to termination or alternative sanctions (42 CFR §§ 488.604 - 488.610).

<sup>12</sup> 42 CFR §§ 494.80 and 494.90.

<sup>13</sup> The Act, §§ 1835(a)(2)(B), 1861(s)(2)(F), and 1881(b)(14)(B).

<sup>14</sup> The Act, § 1833(e); 42 CFR §§ 424.5(a)(6) and 494.170.

<sup>15</sup> The Act § 1128J(d); 42 CFR §§ 401.301-401.305; 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

claims determinations, submit amended cost reports, or use any other appropriate reporting process.<sup>16</sup>

### **Dialysis Clinic, Inc.**

DCI opened in 1971, is headquartered in Nashville, Tennessee, and is the largest nonprofit dialysis provider in the United States. During calendar year (CY) 2018 (audit period), DCI employed over 5,000 staff to serve more than 18,000 patients in more than 240 facilities and nearly 150 hospital services programs across 28 States. DCI has served patients over the last 50 years providing dialysis services, as well as conducting research and education in the field of kidney disease.

DCI's Corporate Executive Committee issued corporate-wide policies and procedures establishing the fundamentals of documentation in the medical record,<sup>17</sup> procedures of documentation related to billing by discipline,<sup>18</sup> procedures of documentation and accountability for the accuracy of medication administered and billed,<sup>19</sup> and an accounts receivable and billing manual,<sup>20</sup> among other centralized policies and procedures to provide caregivers with a standard of documenting in the medical record.

### **HOW WE CONDUCTED THIS AUDIT**

Our audit covered 112,192 claims for dialysis services provided during the audit period for which DCI received Medicare reimbursement totaling \$276.4 million for services performed in patients' homes or in any of DCI's dialysis facilities. We reviewed a random sample of 100 claims.<sup>21</sup> We obtained medical records for each sample item to determine whether services complied with Medicare requirements. We submitted these medical records to an independent medical review contractor that determined whether services were medically reasonable and necessary and met Medicare requirements. We also reviewed DCI's corporate-wide policies and procedures related to medical record documentation and billing Medicare for dialysis treatments.

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<sup>16</sup> 42 CFR §§ 401.305(d), 405.980(c)(4), and 413.24(f); CMS, Provider Reimbursement Manual—Part 1, Pub. No. 15-1, § 2931.2; 81 Fed. Reg. at 7670.

<sup>17</sup> DCI procedure 301 issued on May 1, 2015, "*Fundamentals of Documentation in the Medical Record.*"

<sup>18</sup> DCI procedure 302 issued on May 1, 2015, "*Documentation Related to Billing by Discipline.*"

<sup>19</sup> DCI procedure 303 issued on May 1, 2015, "*Documentation and Accountability for the Accuracy of Medication Administered and Billed.*"

<sup>20</sup> *DCI Accounts Receivable Billing Manual.*

<sup>21</sup> A claim consists of all dialysis services furnished to an individual beneficiary by a dialysis facility during a calendar month (*Medicare Claims Processing Manual*, chapter 8 § 50.3 and chapter 1 § 50.2.2).

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix A contains the details of our audit scope and methodology, Appendix C contains our statistical sampling methodology, and Appendix D contains our sample results and estimates.

## FINDINGS

DCI claimed reimbursement for dialysis services that did not comply with Medicare requirements for 70 of the 100 sampled claims. Specifically,

- For 57 claims, comprehensive assessments or plans of care did not meet Medicare requirements.
- For 15 claims, dialysis treatments were not completed.
- For 17 claims, dialysis services (e.g., dialysis treatments and drugs) were not documented in the medical records.
- For 12 claims, the associated beneficiary's height or weight were not taken in accordance with Medicare requirements.
- For two claims, the medical record did not have a monthly progress note by a physician or other qualified professional.

The total exceeds 70 because 25 of the sampled claims contained more than 1 error.

While DCI had established corporate-wide internal controls to monitor and maintain complete, accurate, and accessible medical records at all its facilities, these controls were not always effective in ensuring that DCI's claims for dialysis services complied with Medicare requirements.

Many of the errors we identified did not affect the Medicare reimbursement DCI received because Medicare pays for dialysis on a bundled per treatment basis or because the findings relate to Medicare CfCs, which are safety and quality standards (e.g., patient assessment, patient plan of care, care at home, medical records, etc.) for improving quality and protecting

the health and safety of beneficiaries.<sup>22</sup> These findings, however, could have a significant effect on the quality of care DCI provided to Medicare beneficiaries and may have resulted in inappropriate or unnecessary treatments.

The combined net overpayments on our sampled claims totaled \$21,669. On the basis of our sample results, we estimated, for errors that affected reimbursement,<sup>23</sup> DCI received unallowable Medicare payments of at least \$14 million during the audit period.<sup>24</sup> As of the publication of this report, this amount included claims outside of the 4-year claim reopening period.

## **COMPREHENSIVE ASSESSMENTS AND PLANS OF CARE DID NOT MEET MEDICARE REQUIREMENTS**

An interdisciplinary care team (IDC team) is responsible for providing dialysis patients with individualized, comprehensive assessments of their needs.<sup>25, 26</sup> The comprehensive assessment must be used to develop the patient's plan of care.<sup>27</sup> The IDC team must also develop and implement a written, individualized comprehensive plan of care that specifies the services necessary to address the beneficiary's needs identified in the comprehensive assessment. The plan of care must be signed by all members of the IDC team and the Medicare beneficiary.<sup>28</sup>

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<sup>22</sup> Sometimes safety and quality standards are conditions of payment. For example, as a condition of coverage and payment for home health services, 42 CFR §§ 409.42(d) and 424.22(a)(1)(iii) require that a plan of care be established and periodically reviewed by a physician.

<sup>23</sup> While 70 claims contained services with a total of 125 errors, only 28 of the 70 claims affected DCI's Medicare reimbursement because the claims did not meet Medicare payment requirements.

<sup>24</sup> To be conservative, we recommend recovery of overpayments at the lower limit of a two-sided 90-percent confidence interval totaling \$14,193,677. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

<sup>25</sup> The facility's interdisciplinary care team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian (42 CFR § 494.80).

<sup>26</sup> The assessment must include the patient's current health status and medical conditions, as well as an evaluation of the appropriateness of the dialysis prescription. Additionally, the assessment should evaluate the patient's nutritional status and psychosocial needs, current physical activity level, family support system, suitability for a transplant, the type of dialysis access, and factors associated with anemia and any applicable treatment plans (42 CFR § 494.80).

<sup>27</sup> 42 CFR § 494.80.

<sup>28</sup> If the beneficiary chooses not to sign, that choice must be documented in the plan of care with the reason the signature was not provided (42 CFR § 494.90).

Implementation of the initial plan of care must begin within the later of 30 calendar days after admission to the outpatient dialysis facility or 13 hemodialysis sessions beginning with the first dialysis session. A follow-up reassessment must occur within 3 months after the completion of the initial assessment to provide information to adjust the patient's plan of care.<sup>29</sup> Additional patient assessments must be conducted to update the plan of care. These assessments are required to be conducted at least annually for stable patients (annual patient assessment) and at least monthly for unstable patients (monthly patient assessment).<sup>30</sup> Implementation of monthly or annual updates of the plan of care must be performed within 15 days of the completion of the additional patient assessments specified in § 494.90(b)(2).<sup>31</sup>

For 57 claims, DCI claimed Medicare reimbursement for dialysis services for which the patient assessment (37 claims) or plan of care (41 claims) did not comply with certain Medicare requirements.<sup>32</sup> Instances of noncompliance included patient assessments that: (1) were not updated timely, either annually for stable patients or monthly for unstable patients (32 claims);<sup>33</sup> (2) were not updated 3 months<sup>34</sup> after the initial assessment (3 claims);<sup>35</sup> (3) did not have the initial assessment conducted within the later of 30 days of admission or 13 dialysis treatments (3 claims);<sup>36</sup> and (4) did not meet all the required elements (2 claims).<sup>37</sup> Additionally, we found plans of care that: (1) were not updated timely (23 claims, Figure 1 includes an example on the next page),<sup>38</sup> (2) were not signed by the patient and did not document the reason why the signature was not provided (19 claims), (3) were not signed by all members of the IDC team (6 claims), and (4) did not contain all required elements (3 claims).<sup>39</sup>

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<sup>29</sup> 42 CFR § 494.80(b)(2).

<sup>30</sup> 42 CFR § 494.80(d).

<sup>31</sup> 42 CFR § 494.90 (b)(2).

<sup>32</sup> Total exceeds 57 because 21 claims contained both deficiencies.

<sup>33</sup> Nine of the thirty-two claims were associated to monthly assessments implemented up to 275 days late. Another 22 claims were associated to annual assessments implemented up to 195 days late, and 1 claim did not have a previous assessment documented in the medical record.

<sup>34</sup> To be conservative, a 93-day threshold was used to calculate the 3-month period.

<sup>35</sup> Three claims with the 3-month assessments implemented up to 33 days late.

<sup>36</sup> Three claims with initial assessments implemented up to 67 days late.

<sup>37</sup> Total exceeds 37 because 3 claims contained more than 1 of these deficiencies.

<sup>38</sup> Six claims had the initial plan of care implemented up to 83 days late, and 17 claims did not have the plan of care updated within 15 days of additional assessments and up to 297 days late.

<sup>39</sup> Total exceeds 41 because 7 claims contained more than 1 of these deficiencies.

Although DCI’s corporate-wide control activities included monitoring the timeliness and completeness of the plans of care and patient assessments, these controls were not effective in ensuring that DCI always complied with the Medicare requirements. When scheduling the necessary reassessments and plan of care updates, DCI’s electronic health record system does not schedule based on the completion date of the patient assessment as 42 CFR §§ 494.80(d) and 494.90(b)(2) require; it schedules based on the completion date of the plan of care. DCI explained that it does not consider the assessment completed until the care plan meeting. It is during these monthly or annual care plan meetings that team members validate each other’s assessments and then create new plan of care goals together with the physician and patient.

Also, DCI facilities have a staff member responsible for auditing medical records at least annually and communicating with the IDC team when plans of care are due or not signed. However, for claims that did not have all required elements in the patient assessments, DCI explained that the incomplete sections were due to a vacancy in the position or the staff member being on extended leave. DCI explained that it does not have a written policy for the vacancies or extended leave; however, it intends to cover extended absences with other staff, sometimes from a different location.

DCI’s failure to ensure plans of care and patient assessments complied with Medicare requirements did not result in improper Medicare payments; however, it could result in quality-of-care issues due to inadequate treatment planning and could preclude beneficiaries from receiving needed services when changes in the patient's condition are not timely identified in these documents and addressed with measurable and expected outcomes and estimated timetables to achieve these outcomes.

**Figure 1: Example of the Assessments and Plan of Care for a Stable Patient That Were Not Completed in Accordance With Medicare Required Timelines**



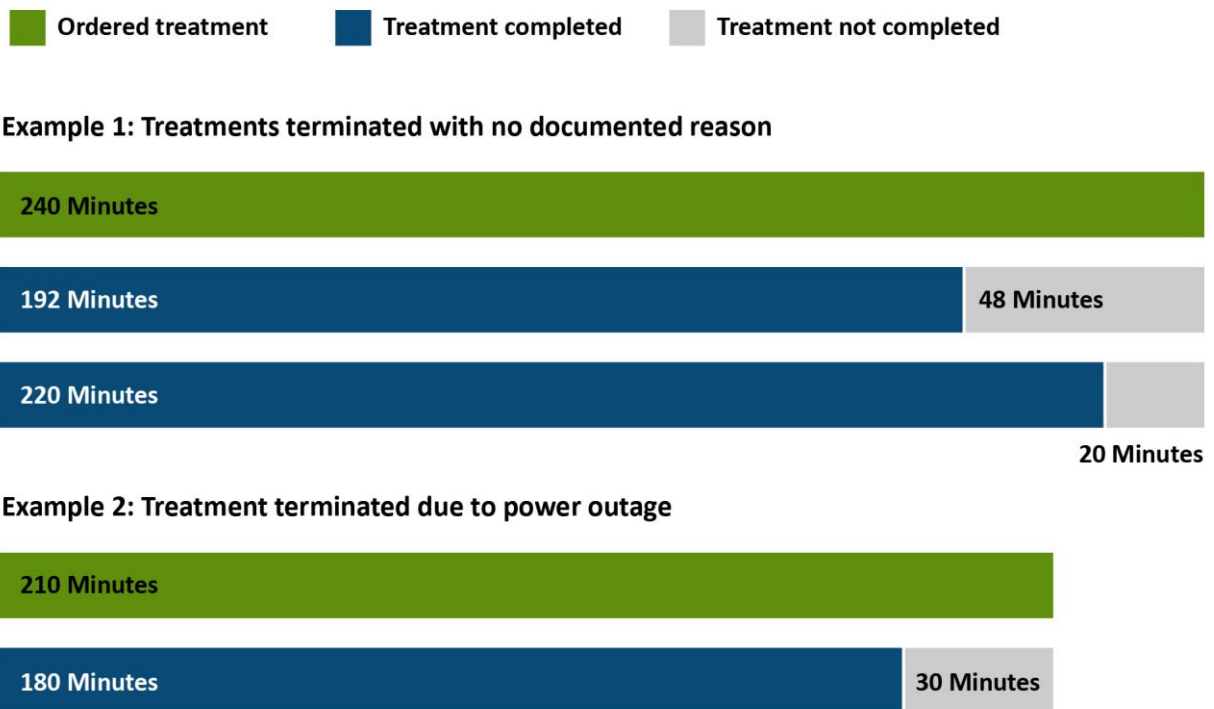
**DIALYSIS TREATMENTS NOT COMPLETED**

No payment shall be made to any provider of Medicare services unless there has been furnished such information as may be necessary in order to determine the amounts due such

provider.<sup>40</sup> In this respect, dialysis facilities must maintain complete, accurate, and accessible records on all patients and, as appropriate, must furnish such information to determine whether payment is due and the amount of such payment.<sup>41</sup> If a dialysis treatment is started but not completed for some unforeseen reason, and a valid reason is documented in the medical record, the provider is paid based on CMS’s base rate for ESRD services. This is a rare occurrence and must be medically justified.<sup>42</sup>

For 15 claims, DCI billed for dialysis treatments that were discontinued 10 or more minutes prior to the beneficiary’s complete treatment and for which the beneficiary’s medical record did not document a valid reason (e.g., a medical emergency when the patient must be rushed to an emergency room) for discontinuing treatment or the beneficiary’s refusal of treatment.<sup>43</sup>

**Figure 2: Examples of Sample Items With Treatment Not Completed**



<sup>40</sup> The Act, § 1833(e).

<sup>41</sup> 42 CFR §§ 424.5(a)(6) and 494.170.

<sup>42</sup> 81 Fed. Reg. 77834, 77870 (Nov. 4, 2016); and *Medicare Claims Processing Manual*, chapter 8, § 10.2 and *Medicare Benefit Policy Manual*, chapter 11, § 50.A.6.

<sup>43</sup> The patient must be informed of their right to refuse or discontinue treatment (42 CFR § 494.70(a)(5)).

While DCI reported having corporate-wide internal controls for documenting the medical reason for discontinuing treatment or a beneficiary's refusal of treatment, these controls were not effective in ensuring that DCI staff always complied with them. DCI staff were required to report the time the treatment was terminated, how many hours or minutes the patient came off early, and the reason for the early termination (including a consent form signed by the patient). For those individuals whom DCI staff identify as consistently noncompliant with prescribed treatment durations, a problem note should be entered with action steps in the plan of care. However, for these treatments, DCI staff did not report the: (1) health complications or medical reason to discontinue treatment, (2) issues of noncompliance with the prescribed treatment duration in the care plan, or (3) patient's consent to discontinue treatment. In October 2019, DCI started implementing a progress note module within its electronic health record system to assist staff in viewing and documenting early termination.

DCI improperly claimed \$6,082 of Medicare reimbursement for incomplete dialysis treatments that were terminated without a documented reason or for invalid reasons, including a holiday or a power outage without rescheduling the missing treatments for the same day, as shown in Figure 2. Dialysis treatments not completed as prescribed could be detrimental to the beneficiary's health and could lead to quality of care issues, such as fluid overload and metabolic problems.<sup>44</sup> Specifically, the medical review contractor determined that the reduced time on dialysis for either missed or shortened treatments could be associated with increased hospitalizations, increased morbidity, and increased mortality.

## **DIALYSIS SERVICES NOT DOCUMENTED**

No payment shall be made to any provider of Medicare services unless there has been furnished such information as may be necessary in order to determine the amounts due such provider.<sup>45</sup> In this respect, dialysis facilities must maintain complete, accurate, and accessible records on all patients and, as appropriate, must furnish such information to determine whether payment is due and the amount of such payment.<sup>46</sup> Dialysis facilities that have been certified to provide dialysis services in patients' homes must ensure that the services are equivalent to services provided within a dialysis facility.<sup>47</sup> The facilities must retrieve and review patients' self-monitoring data and other information, and maintain it in the patients' medical records.<sup>48</sup>

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<sup>44</sup> NIH clinical research on the effects of shortening dialysis sessions by more than 10 minutes can be accessed at Nonadherence in Hemodialysis Patients and Related Factors: A Multicenter Study - PMC (nih.gov), accessed on March 1, 2022.

<sup>45</sup> The Act, § 1833(e).

<sup>46</sup> 42 CFR §§ 424.5(a)(6) and 494.170.

<sup>47</sup> 42 CFR § 494.100.

<sup>48</sup> 42 CFR §§ 494.100(b)(2) and (3).



For 17 claims, DCI billed for dialysis services for which it did not provide documentation to support some services. For 13 of the 17 claims, DCI did not provide dialysis treatment notes during 162 in-home dialysis sessions associated with 11 claims and 2 in-center<sup>49</sup> dialysis sessions associated with 2 claims. For 6 of the 17 claims, DCI did not provide documentation to support the dispensing or administration of medication billed. Specifically, during 33 dates of service<sup>50</sup> associated with all 6 claims (31 in-center and 2 home services), DCI billed more medication than the amount prescribed,<sup>51</sup> and during 4 dates of service associated with 2 of the 6 claims (3 in-center and 1 home services), DCI did not have medical record notes to support the administration and dispensing of the medication billed.<sup>52</sup>

**Table 1: Breakout of Sample Items Between In-Center and Home Dialysis for Dialysis Services Not Documented**

Findings for Documentation	In-Center Dialysis Sample Items	Home Dialysis Sample Items
Did not provide treatment notes for dialysis services billed	2 sessions (2 claims)	162 sessions (11 claims)
Billed more medication than the amount prescribed or were not prescribed	31 date of services (4 claims)	2 date of services (2 claims)
Did not provide notes for drugs billed	3 date of services (1 claim)	1 date of service (1 claim)

Although DCI’s corporate-wide controls included monitoring and maintaining complete, accurate, and accessible records on in-center and in-home patients, these controls were not effective in ensuring DCI staff always complied with them. Specifically, DCI internal control procedures require that if any of the treatment information is missing or incorrectly documented on the patient treatment flowsheet, the flowsheet must be returned to the clinic charge nurse for correction before the treatment can be billed. For home patients, procedures require that if there is questionable or incomplete documentation (e.g., flowsheets) by the patient, the home training nurse must contact the patient to verify information and document that education was given regarding total completion of the patient’s home treatment record.

<sup>49</sup> The 162 in-home sessions included 1 hemodialysis treatment and 161 peritoneal dialysis treatments. The two in-center sessions included only hemodialysis treatments.

<sup>50</sup> These are cases in which the drug dosage billed exceeds the amount prescribed and administered.

<sup>51</sup> One sample case did not have a prescription for services billed.

<sup>52</sup> Total exceeds 6 (and 17) because 2 claims contained more than 1 of these deficiencies.

DCI controls were not effective in ensuring DCI staff always documented dialysis treatments and drugs billed for 17 sampled claims. As a result, DCI received \$15,379 in improper payments for home dialysis services not documented in the medical record. Prior to our audit, DCI had implemented a procedure instructing staff on how to change medication orders to reduce errors in documentation and billing. Additionally, DCI's electronic health record system has an integrated prescription event module for home dialysis patients to account for cases in which the drugs are not administered by the staff in the clinic. This module has the ability to send the prescription to a pharmacy near the patient's home, tracking when the drugs were requested, and the quantity dispensed. Despite these controls, DCI lacked documentation for 17 sample claims. Failure to document home dialysis services demonstrates lack of proper supervision and monitoring of the beneficiary's treatment, which could result in quality-of-care issues by rendering inadequate treatments.

### **HEIGHT AND WEIGHT MEASUREMENTS DID NOT COMPLY WITH MEDICARE REQUIREMENTS**

No payment shall be made to any provider of services unless there has been furnished such information as may be necessary to determine the amounts due such provider.<sup>53</sup> Dialysis facilities must maintain complete, accurate, and accessible records on all patients.<sup>54</sup> CMS adjusts the bundled payment for dialysis services to account for patient age, height, and weight, among other factors.<sup>55</sup> Height and weight are measurements needed to calculate a dialysis patient's body size, which is closely associated with the duration and intensity of dialysis services.<sup>56</sup> Although height and weight are taken at intervals throughout any given month of dialysis treatment, a dialysis patient's weight must be taken immediately following the last dialysis session of the month, and the patient's height must be measured no less frequently than once per year.<sup>57</sup>

For 12 claims, DCI claimed dialysis services for which weight (11 claims) and height (1 claim) measurements did not comply with Medicare requirements. Specifically, for nine claims, a beneficiary had not been weighed immediately following the last home dialysis session of the

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<sup>53</sup> The Act § 1833(e); 42 CFR § 424.5(a)(6).

<sup>54</sup> 42 CFR § 494.170.

<sup>55</sup> The Act § 1881(b)(14)(D)(i); 42 CFR § 413.235; *Medicare Claims Processing Manual*, chapter 8, § 20.1.

<sup>56</sup> 75 Fed. Reg. 49030, 49034-49035 (Aug. 12, 2010); *Medicare Benefit Policy Manual*, chapter 11, § 60.A.3.

<sup>57</sup> 80 Fed. Reg. 68968, 68986-68989 (Nov. 6, 2015); 75 Fed. Reg. 49030, 49089-49090 (Aug. 12, 2010); *Medicare Benefit Policy Manual*, chapter 11 § 60.A.3; and *Medicare Claims Processing Manual*, chapter 8, § 50.3.

month.<sup>58, 59, 60</sup> For two claims, the beneficiary's weight recorded during the last treatment of the month was inaccurately reported because DCI used the weight taken during the beneficiary's last visit at the clinic, resulting in \$210 of improper payments.<sup>61</sup> For another claim, the weight reported on the claim for the last treatment of the month was not supported by the beneficiary's medical records.<sup>62, 63</sup> In addition, for one claim, more than 1 year had passed since DCI documented that it measured the associated beneficiary's height.<sup>64, 65, 66</sup>

While DCI had corporate-wide internal controls regarding height and weight measurements, these controls were not effective in ensuring that DCI always complied with the Medicare requirements. DCI had policies in place requiring staff to review an auto-generated month end email of outstanding items to ensure all patients have a recorded height and post-treatment weight entered during the billing month. However, the list of outstanding items did not require a post-treatment weight during the last treatment session of the month for home patients, and as a result DCI used the most recent weight taken during the last clinic visit of the month.

As a result, for 2 claims DCI received \$210 of improper payments, and for the remaining 10 claims in which the associated height and weight measurements were not taken within the required timeframes, OIG could not determine whether these errors had an impact on DCI's Medicare reimbursement because the measurements needed to determine the correct reimbursement were not available in the medical record. Inaccurate height or weight

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<sup>58</sup> Height and weight measurements are clinical parameters that are critical to establishing the ideal treatment for a dialysis patient. Accordingly, inaccurate height or weight measurements could result in a beneficiary receiving inappropriate dialysis treatments.

<sup>59</sup> Home dialysis patients are given a scale so they can weigh themselves before and after each dialysis treatment. The patient is responsible for documenting their weight on a flowsheet that the patient provides to DCI for inclusion in the medical record.

<sup>60</sup> OIG could not determine whether these errors had an impact on DCI's Medicare reimbursement because the measurements needed to determine the correct reimbursement were not available in the medical record.

<sup>61</sup> For two of the claims, DCI reported the weight measurement taken during the patient's clinic visit early in the claim period; however, the medical record showed the weight measurement taken during the last dialysis session of said period, which was different for both claims.

<sup>62</sup> The other claim did not have a flowsheet to support the weight measurement on the claim.

<sup>63</sup> OIG could not determine the impact on DCI's Medicare reimbursement because the measurements needed to determine the correct reimbursement were not available in the medical record.

<sup>64</sup> Height measurements were documented as taken 67 days after the 1-year requirement.

<sup>65</sup> Total exceeds 12 because 1 claim contained more than 1 of these deficiencies.

<sup>66</sup> OIG could not determine the impact on DCI's Medicare reimbursement because the measurements needed to determine the correct reimbursement were not available in the medical record.

measurements could result in quality of care issues such as a beneficiary receiving inadequate dialysis treatments.

### **LACK OF PHYSICIAN'S MONTHLY PROGRESS NOTES IN THE MEDICAL RECORDS**

Dialysis facilities must ensure that all dialysis patients are seen by a physician, or a qualified practitioner, including a nurse practitioner, clinical nurse specialist, or physician's assistant providing ESRD care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while a hemodialysis patient is receiving in-facility dialysis.<sup>67</sup> Dialysis facilities must maintain complete, accurate, and accessible records on all patients.<sup>68</sup>

For two claims, there was no documentation in the medical record to support that beneficiaries were seen by a physician or other qualified practitioner at least monthly. While DCI had corporate-wide policies and internal controls requiring written monthly progress notes for all problems identified on the plan of care by a physician or other qualified practitioner, these controls were not effective in ensuring that DCI always complied with Medicare requirements. In October 2019, DCI started to implement new controls that included an electronic encounter note module to help practitioners complete progress notes and track documentation of pertinent data.

As a result, lack of monthly monitoring by a physician or qualified practitioner could impact the quality of care associated with the services rendered to Medicare beneficiaries. A patient's periodic visits (at least one per month) allow the physician to ascertain whether the dialysis is working well and whether the patient is physiologically and psychologically tolerating the procedure.

### **CONCLUSION**

The combined net overpayments on our sampled claims totaled \$21,669. On the basis of our sample results, we estimated that DCI received unallowable Medicare payments of at least \$14,193,677 for our audit period. As of the publication of this report, this amount included claims outside of the Medicare 4-year claim-reopening period. We note that, while these identified payments are only about 5 percent of total Medicare reimbursement for the period, the errors we identified could have a significant impact on the quality of services that DCI is providing to Medicare beneficiaries.

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<sup>67</sup> 42 CFR § 494.90(b)(4).

<sup>68</sup> 42 CFR § 494.170.

## RECOMMENDATIONS

We recommend that Dialysis Clinic, Inc.:

- refund to the Federal Government the portion of the estimated \$14,193,677 in improper payments for claims incorrectly billed to the Medicare program that are within the 4-year reopening period;<sup>69</sup>
- based on the results of this audit, exercise reasonable diligence to identify, report, and return any overpayments in accordance with the 60-day rule<sup>70</sup> and identify any of those returned overpayments as having been made in accordance with this recommendation;
- modify its medical record system to ensure that patient assessments and plans of care are completed and updated timely based on the completion date of the last assessment as required, to ensure all the required elements and signatures are included, and implement written policies and procedures to ensure staff availability during extended leave or vacancies;
- modify its internal controls to ensure that weight measurements for home dialysis patients noted in beneficiaries' electronic health records are taken at the last documented dialysis treatment of the month;
- reinforce, through staff and beneficiary training, its internal controls on how to maintain proper documentation of dialysis services in the medical record; and
- reinforce, through staff training, its internal controls for: (1) documenting the discontinuance of dialysis treatments and rescheduling any incomplete treatment, (2) ensuring that height and weight measurements are correctly recorded in the medical records before submitting Medicare claims, and (3) documenting physicians' monthly progress notes.

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<sup>69</sup> OIG audit recommendations do not represent final determinations by Medicare. CMS, acting through a MAC or other contractor, will determine whether overpayments exist and will recoup any overpayments consistent with its policies and procedures. Providers have the right to appeal those determinations and should familiarize themselves with the rules pertaining to when overpayments must be returned or are subject to offset while an appeal is pending. The Medicare Part A and Part B appeals process has five levels (42 CFR § 405.904(a)(2)), and if a provider exercises its right to an appeal, the provider does not need to return overpayments until after the second level of appeal. Potential overpayments identified in OIG reports that are based on extrapolation may be re-estimated depending on CMS determinations and the outcome of appeals.

<sup>70</sup> This recommendation does not apply to any overpayments that are both within our sampling frame (i.e., the population from which we selected our statistical sample) and refunded based upon the extrapolated overpayment amount. Those overpayments are already covered in the previous recommendation.

## **DIALYSIS CLINIC, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, DCI, through its attorneys, did not concur with our recommendations but described actions it has taken and plans to take to address some of them. DCI disagreed with our findings and stated that the methodological and substantive deficiencies of the draft report make the findings largely invalid. DCI disputed the validity of the financial determinations in the draft report and believed purported overpayments we identified to be unsubstantiated based on the medical record, unsupported by the pertinent guidance, or both. Specifically, DCI stated that the draft report did not accurately consider the nature of DCI's corporate structure and placed an undue emphasis on its tax identification number, as opposed to the unique provider numbers and Medicare certifications of each clinic. DCI stated that although it maintains a number of enterprise-wide clinical and business functions, individual facility operations and clinical practices are ultimately local matters. In addition, DCI stated that its clinics are divided among 51 geographically bounded business units, each of which is managed by its own area operations director.

Finally, DCI stated that our extrapolation method for the overpayments is unreliable and statistically invalid because it is based on a flawed sample design. Moreover, DCI stated that because we failed to draw a statistically valid sample, it is inappropriate to extrapolate the results from the sample to the overall universe of claims.

After reviewing DCI's comments, we revised our determinations for 15 claims and adjusted our related recommendations accordingly. We maintain that our findings and recommendations, as revised, are valid. We also maintain that our sampling methodology was valid.

A summary of DCI's comments and our responses follows. DCI's comments appear as Appendix G. We excluded attachments (which DCI identified as Exhibit A or Expert Report) because they contained personally identifiable information. We are separately providing DCI's comments and attachments in their entirety to CMS.

### **COMPREHENSIVE ASSESSMENTS AND PLANS OF CARE DID NOT MEET MEDICARE REQUIREMENTS**

#### **Dialysis Clinic, Inc., Comments**

DCI disagreed with our findings and provided comments for 19 of the 57 claims in error: specifically, 16 claims with errors associated with comprehensive assessments and 10 claims with errors in the plans of care.<sup>71</sup> Nevertheless, DCI stated that its clinics will implement our recommendations accordingly.

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<sup>71</sup> The total exceeds 19 because 7 claims contained both deficiencies.

## Office of Inspector General Response

We reviewed DCI's comments and noted that arguments for 12 of the 19 claims were not associated with the errors we reported. Specifically, for seven claims, DCI's comments addressed areas associated to the plan of care; however, our findings were related to errors in the comprehensive assessments.<sup>72</sup> For another four claims, DCI's comments addressed areas associated to the elements of the plan of care; however, our findings were related to timely updates in the comprehensive assessment or plan of care and/or missing signatures in the plan of care.<sup>73</sup> Lastly, for one claim, DCI's comments addressed updates to the plan of care; however, our findings were related to the comprehensive assessment not updated timely and plan of care not signed by all members of the IDC team.<sup>74</sup>

For example, for sample claim 13, the error reported was associated with the untimely update to the comprehensive assessment, not to the plan of care as indicated in DCI's comments. Specifically, this claim had an assessment completed on November 16, 2016, for a stable patient, and the next assessment was completed January 3, 2018; as result, the assessment was late by 48 days over the 365-day threshold for an annual update for stable patients.

After reviewing DCI's comments for the 12 claims in which DCI addressed incorrect reasons for the errors reported, we maintain that our findings are valid. For the remaining seven claims, we also maintain that our findings are valid. Specifically, after reviewing DCI's comments for these seven claims, we found these claims had a comprehensive assessment that was not updated timely, either annually for stable patients or monthly for unstable patients (four claims);<sup>75</sup> a comprehensive assessment that was not updated 3 months after the initial assessment (two claims);<sup>76</sup> a comprehensive assessment that did not contact all the required elements (two claims);<sup>77</sup> a plan of care that was not updated timely (two claims);<sup>78</sup> a plan of

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<sup>72</sup> Sample claims 12, 13, 25, 40, 50, 73, and 78.

<sup>73</sup> Sample claims 30, 36, 43, and 46.

<sup>74</sup> Sample claim 81.

<sup>75</sup> Sample claims 53, 60, 80, and 97.

<sup>76</sup> Sample claims 10 and 60.

<sup>77</sup> Sample claims 96 and 97.

<sup>78</sup> Sample claims 53 and 60.

care that was not signed by all members of the IDC team (one claim);<sup>79</sup> or a plan of care that did not contain all required elements (two claims).<sup>80, 81</sup>

For example, for sample claim 10, DCI indicated that our finding was incorrect, and the 3-month follow-up assessment was updated timely through DCI's electronic health record system, which schedules the due date for assessments and care plan updates in 3-month increments measured from the initial care plan due date, including assessments to be completed prior to the plan of care. In response to DCI's comments, as previously discussed with DCI's management and described in the draft report, when scheduling the necessary reassessments and plan of care updates, DCI's electronic health record system does not schedule based on the completion date of the patient assessment as 42 CFR §§ 494.80(d) and 494.90(b)(2) require; it schedules based on the completion date of the plan of care. Therefore, an initial assessment was completed on July 22, 2017, and the next assessment was completed on October 31, 2017; as result, the assessment was late by 8 days over the 3-month period.<sup>82</sup>

As we described in the draft report, failure to ensure that plans of care and patient assessments complied with Medicare requirements could result in quality-of-care issues due to inadequate treatment planning and could preclude beneficiaries from receiving needed services.

Therefore, we continue to recommend that DCI modify its medical record system to ensure that the patient assessments and plans of care are completed and updated timely based on the completion of the last assessment, ensure all the required elements and signatures are included, and implement written policies and procedures to ensure staff availability during extended leave or vacancies.

## **DIALYSIS TREATMENTS NOT COMPLETED**

### **Dialysis Clinic, Inc., Comments**

DCI disagreed that early discontinuation of properly ordered services has material impact on payment, particularly when the patient receives adequate dialysis as measured by Medicare-recognized laboratory values (i.e., the Kt/V formula). DCI also stated that the standard for early discontinuation articulated in the report was erroneous and in direct contravention of other Federal ESRD policies. DCI argued that reporting of treatment time is not a condition to payment. In other words, prospective payment is triggered when treatment commences, irrespective of when the treatment ends.<sup>83</sup> There is no payment consequence for infrequent

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<sup>79</sup> Sample claim 96.

<sup>80</sup> Sample claims 76 and 80.

<sup>81</sup> The total exceeds seven claims because five claims have more than one deficiency.

<sup>82</sup> To be conservative, a 93-day threshold was used to calculate the 3-month period to update the comprehensive assessment after 3 months of the initial assessment.

<sup>83</sup> DCI cites the *Provider Reimbursement Manual – Part 1*, ch. 27, § 2702.1(A-B) as support for this statement.



occasions when a patient’s treatment does not last the prescribed length, since the ESRD prospective payment rate is not dependent upon the time period associated with the actual dialysis treatment itself.<sup>84</sup> Moreover, DCI stated that any requirement to report time would violate the holding in *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019). Nevertheless, DCI stated that its clinics will continue to reinforce, through training and remediation efforts, its internal controls for documenting the discontinuance of dialysis treatments and for rescheduling any incomplete treatments. Additionally, DCI will continue to educate patients on the importance of adherence to the prescribed duration of the treatments.

### **Office of Inspector General Response**

Based on DCI’s comments, we revised our determination and financial disallowance for 11 claims in their entirety and partially for another 4 of the 26 claims originally found to be in error because the medical record may indicate a reason for discontinuing treatment, such as hypotension, cramps, pregnancy, or patient request. Otherwise, we maintain that 15 of the 26 claims remain valid.<sup>85</sup>

DCI asserts that early discontinuation of properly ordered dialysis services has no material impact on payment because adequate dialysis is measured by “Medicare-recognized laboratory values (i.e., the Kt/V formula).” CMS uses these lab values as part of the ESRD Quality Incentive Program, not as a parameter for payment.

DCI asserted that reporting of treatment time is not a condition of payment and contrary to *Azar v. Allina*; however, we did not question these 15 claims based upon the failure to meet any Medicare requirement to record the length of the service. In this audit, we questioned these 15 claims because Medicare pays a composite rate per treatment<sup>86</sup> that comprises all outpatient renal dialysis services to be provided during that treatment,<sup>87</sup> and the dialysis services (i.e., the treatments) provided by DCI were incomplete as they were discontinued earlier than ordered.<sup>88</sup> In the claims we questioned, DCI documented that it did not provide the

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<sup>84</sup> DCI cites the *Provider Reimbursement Manual – Part 1*, ch. 27, § 2702.1(A-B) and 81 Fed. Reg. 77834, 77870 (Nov. 4, 2016) as support for this statement.

<sup>85</sup> The total claims discussed in this section exceed 26 claims in error because 4 claims had at least 1 date of service on the claim revised, but not all dates of service on the claim were revised.

<sup>86</sup> The Act § 1881(b)(14); 42 CFR § 413.215.

<sup>87</sup> The Act § 1881(b)(14)(B)(i); 42 CFR §§ 413.171, 413.215(a), and 413.217(a). Outpatient renal dialysis services include maintenance dialysis treatments and all associated services including historically defined dialysis-related drugs, laboratory tests, equipment, supplies, and staff time (75 Fed. Reg. 49030, 49036 (Aug. 12, 2010); 74 Fed. Reg. 49922, 49928 (Sept. 29, 2009)).

<sup>88</sup> Medicare does not pay for services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). Payment for dialysis services will only be made if a physician certifies that the services are or were medically required (the

entire treatment; rather, it documented that the treatments were terminated early. Medicare pays for dialysis on a per treatment basis without providing for pro rata payments when services are not provided as ordered and billed.<sup>89</sup> Furthermore, DCI is incorrect in asserting that a prospective payment is triggered when the treatment commences, irrespective of when the treatment ends. DCI states that section 2702 of the *Provider Reimbursement Manual – Part 1* supports its argument, but it does the opposite. Indeed, it states, “under the composite rate payment system, the patient’s ESRD facility must furnish all of the necessary dialysis services, equipment, and supplies. \* \* \* If it fails to furnish . . . any part of the items and services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that it furnished.”<sup>90</sup> The only exception is when a treatment is not completed for some unforeseen, but valid reason, that is fully documented.<sup>91</sup>

We maintain that our findings as revised are valid. Therefore, we continue to recommend that DCI reinforce, through staff training, its internal controls for documenting the discontinuance of dialysis treatments and reschedule any incomplete treatment.

## **DIALYSIS SERVICES NOT DOCUMENTED**

### **Dialysis Clinic, Inc., Comments**

DCI disagreed with our findings generally and provided additional comments for 8 of the 17 claims in error. DCI stated that our findings are inconsistent with Congressional intent stated in the Act, § 1881(c)(6): (“It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated and that the maximum practical number...”) and policy directives of the past two presidential administrations. DCI also noted that patient-generated documentation is primarily relevant to assessing quality of care under the CfCs, which are enforced through routine surveys by State certification agencies. DCI believes that the finding will have a chilling effect on the expansion of home dialysis modalities, which all stakeholders—patients, payors, policymakers, and clinicians—agree are clinically beneficial to patients and the Medicare program. Finally, DCI asserted that since the time of the audit and in conformity with

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Act, §§ 1835(a)(2)(B) and 1861(s)(2)(F)). For each claim we questioned, the physician had ordered a specific number of minutes of dialysis services (e.g., 240 minutes or 210 minutes) that the physician determined medically necessary.

<sup>89</sup> The Act § 1881(b)(14)(B)(i); 42 CFR §§ 413.171, 413.215(a), and 413.217(a).

<sup>90</sup> This is reiterated in the *Medicare Claims Policy Manual*, ch. 8, § 10.1, where CMS states, “Under the composite rate payment system, the patient’s ESRD facility must furnish all of the necessary dialysis services, equipment, and supplies. \* \* \* If the facility fails to furnish . . . any part of the items or services covered under the rate, then the facility cannot be paid any amount for the part of the items and services that it furnishes.”

<sup>91</sup> *Provider Reimbursement Manual – Part 1*, ch. 27, § 2702.1(A). The *Medicare Claims Processing Manual*, chapter 8, § 10.2 and *Medicare Benefit Policy Manual*, chapter 11, § 50.A.6., that we referenced in footnote 42 say the same thing.

our recommendations, it continued to emphasize and re-emphasize—through training, pre-programmed electronic records protocol, and beneficiary outreach—how and why beneficiaries and staff must create, maintain, and deliver proper documentation of dialysis treatments, with special emphasis on at-home treatments and the accompanying patient-generated documentation.

### **Office of Inspector General Response**

After reviewing DCI's comments, we maintain that our findings are valid. Specifically, we found these claims had billed more medication than the amount prescribed and administered (two claims),<sup>92</sup> billed dialysis treatments that did not have treatment notes in the medical record (four claims),<sup>93</sup> and billed medication that did not have evidence in the medical record that services were provided (two claims).<sup>94</sup>

For example, for sample claim 2, DCI disagreed with our finding that DCI did not provide documentation to support the medications billed for this patient. Specifically, DCI indicated that the Sensipar listed as 1800 Serv. Units on the claim had a documented prescription. In response to DCI's comments, we questioned services associated with the Venofer services billed, for which there was no evidence in the medical record to support that drug services billed were ordered and rendered.

As we described in the draft report, DCI billed for 17 claims for dialysis services for which it did not provide documentation to support some services. The Act, § 1833(e) and 42 CFR § 424.5(a)(6) require such information as may be necessary to determine whether payment is due. Without documentation of a service, there can be no payment. Therefore, we continue to recommend that DCI reinforce, through staff and beneficiary training, its internal controls on how to maintain proper documentation of dialysis services in the medical record.

## **HEIGHT AND WEIGHT MEASUREMENTS DID NOT COMPLY WITH MEDICARE REQUIREMENTS**

### **Dialysis Clinic, Inc., Comments**

DCI disagreed with our findings, stating that its clinical requirements with respect to height/weight measurements are consistent with Medicare guidance. Moreover, DCI argued that many of the same issues with patient-generated documentation described in finding 3

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<sup>92</sup> Sample claim 14 Hecetrol and sample claim 34 Sensipar.

<sup>93</sup> Sample claims 10, 28, 44, and 55. Please note these sample claims had some monthly encounter notes at the clinic; however, there was no indication that the patient received dialysis treatments during these visits. Therefore, the medical record did not include a daily treatment log for the service dates, and it was not provided upon request.

<sup>94</sup> Sample claim 2 Venofer and sample claim 66 Influenza Vaccine.

were also present for the claims identified under finding 4. Nevertheless, DCI agreed with our recommendation and stated that it continues to seek adherence to existing internal controls and to explore additional opportunities to ensure timely recording of patient data, including patient weights. Additionally, DCI stated that it will continue to emphasize and re-emphasize—through training, pre-programmed electronic records protocol, and beneficiary outreach—how and why beneficiaries and staff must create, maintain, and deliver proper documentation of patient biometric data.

DCI also asserted that the alleged overpayment should be \$209, not \$210. Also, DCI stated that in at least three of the claims we sampled (samples 28, 47, and 90), the weight value submitted on DCI’s claim likely resulted in marginal underpayments to DCI.

### **Office of Inspector General Response**

After reviewing DCI’s comments, we maintain that our findings are valid. In response to DCI’s concerns, we want to clarify that Appendix E showed total errors rounded, and the exact amount used in the projection was \$209.50. CMS adjusts the bundled payment for dialysis services to account for patient age, height, and weight, among other factors. Height and weight are measurements needed to calculate a dialysis patient’s body size, which is closely associated with the duration and intensity of dialysis services. We found 12 errors, but identified improper payment for only 2 because we could not determine whether the other errors had an impact on DCI’s Medicare reimbursement. We also noted concern in the draft report that inaccurate height or weight measurements could result in quality-of-care issues such as a beneficiary receiving inadequate dialysis treatments. Therefore, we continue to recommend that DCI reinforce, through training, its internal controls ensuring that height and weight measurements are correctly recorded in the medical records before submitting Medicare claims.

## **LACK OF PHYSICIAN’S MONTHLY PROGRESS NOTES**

### **Dialysis Clinic, Inc., Comments**

DCI described its clinical systems and internal controls to ensure complete progress notes or alternative documentation of physician physical examinations but did not dispute our finding that for two claims there was no documentation in the medical record to support that beneficiaries were seen by a physician. Nevertheless, DCI agreed with our recommendation to emphasize the importance of documenting physician encounters and encourage its clinics and clinicians to transition toward a more integrated and comprehensive recordkeeping system by adopting the electronic progress note module in their electronic medical records.

### **Office of Inspector General Response**

After reviewing DCI’s comments, we maintain that our findings are valid. As we described in the draft report, lack of monthly monitoring by a physician or qualified practitioner could impact the quality of care associated with the services rendered to Medicare beneficiaries. A

patient's periodic visits (at least one per month) allow the physician to ascertain whether the dialysis is working well and whether the patient is physiologically and psychologically tolerating the procedure.<sup>95</sup> Therefore, we continue to recommend that DCI reinforce, through training, its internal controls for documenting physicians' monthly progress notes.

## STATISTICAL SAMPLING AND EXTRAPOLATION

### Dialysis Clinic, Inc., Comments

DCI challenged the validity of our statistical sampling and extrapolation methodologies, engaged a statistical expert to review our sampling methodology, and provided a copy of the statistical expert's report. DCI stated that our "extrapolation method for the alleged overpayments is unreliable and statistically invalid because it is based on a flawed sample design." According to DCI and the statistical expert: (1) "[d]rawing samples from more than one provider is inconsistent with generally accepted auditing standards, including those used by CMS," (2) "OAS employed a deficient sampling methodology that renders any overpayment calculations unable to be reliably extrapolated to its population of claims," and (3) it is "inappropriate to generalize the results of a miniscule sample of claims covering only a small portion of the company's clinics to the entirety of its operations."

### Office of Inspector General Response

After reviewing the statistical expert's report, we maintain that our sampling and extrapolation methodologies are statistically valid. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.<sup>96</sup> The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>97</sup> We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation.

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<sup>95</sup> 42 CFR § 494.90(b)(4).

<sup>96</sup> See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at \*26-28 (S.D. Tex. 2013), adopted by 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>97</sup> See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at \*34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

We disagree with DCI’s statement that, “[d]rawing samples from more than one provider is inconsistent with generally accepted auditing standards, including those used by CMS.” DCI further stated that “the audit should be focused on the provider, not the entire enterprise—that is, it should be organized by provider number or National Provider Identifier, not tax identification number.” For this specific comment, DCI references CMS’s Medicare Program Integrity Manual (MPIM). The MPIM does not apply to OIG, as acknowledged by DCI on page 5 of its comments letter. In addition, the selection of the provider/supplier is not specifically part of the sample design process, therefore the choice of provider/supplier has no impact upon the statistical validity of the sample design. We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

During our review, we met with DCI to discuss the internal controls applicable to the sample items and per DCI’s responses all clinics had a centralized internal control system using the same set of policies and procedures including the electronic health record system. As result, we identified systematic issues on areas such as how the plan of care and comprehensive assessments were not updated timely due to incorrect interpretation of 42 CFR §§ 494.80(d) and 494.90(b)(2). Essentially, DCI explained that it does not consider the assessment completed until the care plan meeting. Moreover, DCI has a single Employer Identification Number (EIN), a type of Tax Identification Number (TIN) for a business entity. It is our understanding that the individual facilities are not separate legal entities and do not have their own EIN. When billing Medicare, each facility uses its own CMS Certification Number and National Provider Identifier, as well as DCI’s TIN. CMS sends payments for services rendered at each facility to a DCI bank account pursuant to Electronic Fund Transfer (EFT) agreements between each facility and CMS. Moreover, no individual clinic policies and procedures were provided as part of the response.

Additionally, we disagree with the statistical expert’s statements that “OAS employed a deficient sampling methodology that renders any overpayment calculations unable to be reliably extrapolated to its population of claims.” The statistical expert added that our “sampling methodology fails to consider geography and, as a result, leads to a sample that is unrepresentative of the population with respect to geography.” The sample is considered representative of the target population because it was randomly selected from the population (which was completed using a valid random number generator). No other definition of “representative” nor test of “representativeness” is required by the methods outlined in finite sampling textbooks, e.g., Cochran (1977),<sup>98</sup> which were utilized for this audit. Because of this randomness, the sample may not mirror the population in every regard, e.g., by geography or provider. Any variability due to differences in geography or by provider is captured in the

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<sup>98</sup> See e.g., Cochran, William G., *Sampling Techniques*: 3rd edition, Wiley, New York, 1977. The text provides the detailed proofs underlying design-based sampling methods for stratified and simple random sampling used by OIG.

random selection process. One well-founded approach for handling the potential differences between the sample and the population is to rely on the confidence interval rather than the point estimate, which was done in this audit. The confidence interval is designed to cover the actual overpayment amount even in situations where the sample does not exactly match the population.

Finally, we disagree with DCI's statements that it is "inappropriate to generalize the results of a miniscule sample of claims covering only a small portion of the company's clinics to the entirety of its operations" and that "attributing the findings of 100 claims to more than 240 unique providers calls into question the accuracy of OIG's findings." Small sample sizes, e.g., smaller than 100, have routinely been upheld by the Departmental Appeals Board and Federal courts.<sup>99</sup> The legal standard for a sample size is that it must be sufficient to be statistically valid, not that it be the most precise methodology.<sup>100</sup> Note that sample size is incorporated into the computation of the confidence interval, with a smaller sample size generally resulting in a smaller lower limit. Because absolute precision is not required, any imprecision in the sample may be remedied by recommending recovery at the lower limit, which was done in this audit.<sup>101</sup> This approach results in an estimate that is lower than the actual overpayment amount 95 percent of the time, and thus it generally favors the provider.<sup>102</sup>

Accordingly, we made no changes to our statistical sampling and estimation methodology in response to DCI's comments.

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<sup>99</sup> See *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012) (upholding a sample size of 95 claims); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 (S.D. Tex. 2012) (upholding a sample size of 30 claims).

<sup>100</sup> See *John Balko & Assoc. v. Sebelius*, 2012 U.S. Dist. LEXIS 183052 at \*34-35 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 at \*17 (S.D. Fla. 2012).

<sup>101</sup> See *Pruchniewski v. Leavitt*, 2006 U.S. Dist. LEXIS 101218 at \*51-52 (M.D. Fla. 2006).

<sup>102</sup> See *Puerto Rico Dep't of Health*, DAB No. 2385, at 10-11 (2011); *Oklahoma Dep't of Human Servs.*, DAB No. 1436, at 8 (1993) (stating that the calculation of the disallowance using the lower limit of the confidence interval gave the State the "benefit of any doubt" raised by use of a smaller sample size).

## APPENDIX A: AUDIT SCOPE AND METHODOLOGY

### SCOPE

Our audit covered 112,192 claims<sup>103</sup> for which DCI received Medicare reimbursement totaling \$276,427,841 for dialysis services provided during our audit period. Claims for these services were extracted from CMS's National Claims History (NCH) file.

We did not review the overall internal control structure of DCI. Rather, we limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of DCI's policies and procedures for documenting and billing Medicare for dialysis services. Our audit enabled us to establish reasonable assurance of the authenticity and accuracy of the data from the NCH file, but we did not assess the completeness of the file.

We performed our fieldwork from December 2019 to June 2021.

### METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidance;
- interviewed officials from First Coast Service Option (the MAC that processed and paid some of the claims submitted by DCI during our audit period) to obtain an understanding of the Medicare requirements related to dialysis services;<sup>104</sup>
- interviewed DCI officials to gain an understanding of DCI corporate-wide policies and procedures for providing dialysis services, maintaining documentation for services provided, and billing Medicare for such services;
- obtained from CMS's NCH file a sampling frame of 112,192 claims totaling \$276,427,841 for our audit period;
- selected a random sample of 100 claims from the sampling frame;
- reviewed data from CMS's Common Working File to determine whether claims associated with the sampled claims had been canceled or adjusted;

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<sup>103</sup> A claim consists of all dialysis services furnished to an individual beneficiary by a dialysis facility during a calendar month (*Medicare Claims Processing Manual*, chapter 8, § 50.3 and chapter 1 § 50.2.2).

<sup>104</sup> For calendar year 2018, DCI had claims processed through multiple Medicare Administrative Contractors.



- obtained medical records and other documentation from DCI for the 100 sampled claims;
- reviewed the medical records and other documentation DCI provided to ensure the sampled claims met Medicare requirements for documentation, including:
  - comprehensive assessments and plans of care,
  - completion of dialysis treatments,
  - documentation of dialysis services in the medical records,
  - billing and/or accurately reporting the beneficiary’s height or weight, and
  - documentation of monthly progress notes by a physician or other qualified professional;
- submitted the medical records and other documentation to an independent medical review contractor that determined whether services were medically reasonable and necessary and met Medicare requirements;
- reviewed the medical review contractor’s results and summarized the reason(s) a claim did not comply with Medicare requirements;
- interviewed DCI officials about the policies and procedures and internal controls for areas of noncompliance;
- used the results of the sample to estimate the amount of improper Medicare payments made to DCI for dialysis services; and
- discussed the results of our audit with DCI officials.

See Appendix C for the details of our statistical sampling methodology and Appendix D for our sample results and estimates.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

**APPENDIX B: RELATED OFFICE OF INSPECTOR GENERAL REPORTS**

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Medicare Dialysis Services Provider Compliance Review: Bio-Medical Applications of Arecibo, Inc.</i>	<a href="#"><u>A-02-17-01016</u></a>	3/25/2020
<i>Dialysis Services Provided by Atlantis Health Care Group of Puerto Rico, Inc., Did Not Comply With Medicare Requirements Intended To Ensure the Quality of Care Provided to Medicare Beneficiaries</i>	<a href="#"><u>A-02-16-01009</u></a>	12/28/2018
<i>Compliance Review of Woburn Dialysis</i>	<a href="#"><u>A-01-12-00516</u></a>	4/30/2014
<i>Compliance Review of Lowell General Hospital's Methuen Dialysis Facility</i>	<a href="#"><u>A-01-12-00517</u></a>	2/6/2014

## **APPENDIX C: STATISTICAL SAMPLING METHODOLOGY**

### **SAMPLING FRAME**

The sampling frame was an Access database containing 112,192 Medicare Part B claims with payments totaling \$276,427,841 for ESRD services provided by DCI during CY 2018 (our audit period). The claims in the sampling frame were not associated with beneficiaries that had multiple claims in a single month and had not been reviewed previously by a CMS contractor.

### **SAMPLE UNIT**

The sample unit was an ESRD claim.

### **SAMPLE DESIGN**

We used a simple random sample.

### **SAMPLE SIZE**

We selected a sample of 100 claims.

### **SOURCE OF THE RANDOM NUMBERS**

We generated the random numbers with the OIG, Office of Audit Services (OAS), statistical software.

### **METHOD FOR SELECTING SAMPLE ITEMS**

We consecutively numbered the claims in the sampling frame from 1 to 112,192. After generating 100 random numbers, we selected the corresponding frame items.

### **ESTIMATION METHODOLOGY**

We used the OIG/OAS statistical software to estimate the total dollar amount of improper Medicare payments made to DCI in the sampling frame during the audit period (Appendix D). To be conservative, we recommend recovery of overpayments at the lower limit of the two-sided 90-percent confidence interval. Lower limits calculated in this manner are designed to be less than the actual overpayment total 95 percent of the time.

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Table 2: Sample Results**

<b>Claims in Frame</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Claims With Errors in Sample</b>	<b>Number of Unallowable Claims Impacting Reimbursement in Sample</b>	<b>Value of Unallowable Claims in Sample</b>
112,192	\$276,427,841	100	\$244,175	70 <sup>105</sup>	28	\$21,669

**Estimated Value of Unallowable Claims in the Sampling Frame  
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$24,311,861
Lower limit	14,193,677
Upper limit	34,430,044

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<sup>105</sup> While 70 claims contained services with an error, only 28 of the 70 claims impacted DCI's Medicare reimbursement.

**APPENDIX E: SUMMARY OF DEFICIENCIES FOR EACH SAMPLED CLAIM**

**Legend**

<b>Major Findings (MF)</b>	<b>Deficiency (D)</b>	<b>Description</b>
MAJOR FINDING 1: Comprehensive Assessments and Plans of Care Did Not Meet Medicare Requirements	1	Comprehensive assessments did not meet Medicare requirements.
	2	Plans of care did not meet Medicare requirements.
MAJOR FINDING 2: Dialysis Treatments Not Completed	3	Dialysis treatment discontinued 10 or more minutes prior to treatment completion and no valid reason documented.
MAJOR FINDING 3: Dialysis Services Not Documented	4	Dialysis services not documented in the medical records (dialysis and drugs).
MAJOR FINDING 4: Height and Weight Measurements Did Not Comply With Medicare Requirements	5	Weight measurements not taken immediately following the last dialysis session of the month.
	6	Weight measurements inaccurately reported on the claim or not supported by the beneficiary's medical records.
	7	Height measurements not documented as taken within the 1-year requirement.
MAJOR FINDING 5: Lack of Physician's Monthly Progress Notes in the Medical Records	8	Lack of monthly progress notes by a physician, or a qualified practitioner.

<b>Major Findings</b>	<b>MF 1</b>		<b>MF 2</b>	<b>MF 3</b>	<b>MF 4</b>			<b>MF 5</b>	<b>Total Overpayments</b>	<b>Number of Deficiencies</b>
	<b>D1</b>	<b>D2</b>	<b>D3</b>	<b>D4</b>	<b>D5</b>	<b>D6</b>	<b>D7</b>	<b>D8</b>		
1	X		257	X				-	257	3
2		X	-	X				-	-	2
3			-	-				-	-	-
4			-	-				-	-	-
5			-	-				-	-	-
6			-	-				-	-	-
7			-	-				-	-	-
8		X	-	287	X			-	287	3
9			-	-				-	-	-
10	X		-	1,125				-	1,125	2
11			-	-				-	-	-
12	X		-	-				-	-	1
13	X		-	-				-	-	1
14	X	X	-	X				-	-	3
15	X	X	-	-				-	-	2
16			167	-				-	167	1

Major Findings Sample Claim	MF 1		MF 2	MF 3	MF 4			MF 5	Total Overpayments	Number of Deficiencies
	D1	D2	D3	D4	D5	D6	D7	D8		
17		X	-	-				-	-	1
18	X		-	-				-	-	1
19			-	-		196		-	196	1
20			-	-				-	-	-
21	X	X	-	-			X	-	-	3
22		X	-	-				-	-	1
23	X		916	-				-	916	2
24		X	-	231				-	231	2
25	X		-	-				-	-	1
26		X	-	-				-	-	1
27			-	-				-	-	-
28			-	1,789	X			-	1,789	2
29	X		-	-				-	-	1
30		X	377	-				-	377	2
31	X	X	-	-				-	-	2
32			-	-				-	-	-
33			-	-				-	-	-
34	X	X	-	X				-	-	3
35		X	-	-				-	-	1
36	X	X	177	-				-	177	3
37		X	-	-				-	-	1
38			-	-				-	-	-
39			-	-				-	-	-
40	X		-	-				-	-	1
41	X	X	-	-				-	-	2
42			-	-				-	-	-
43		X	-	-				-	-	1
44			-	223				-	223	1
45	X		-	-				-	-	1
46	X	X	-	-				-	-	2
47			-	1,009	X			-	1,009	2
48			572	-				-	572	1
49			392	-				X	392	2
50	X		-	749	X			-	749	3
51			-	-				-	-	-
52			-	-				X	-	1
53	X	X	808	-				-	808	3
54			-	-				-	-	-
55	X		-	3,268	X			-	3,268	3
56		X	-	-				-	-	1

Major Findings Sample Claim	MF 1		MF 2	MF 3	MF 4			MF 5	Total Overpayments	Number of Deficiencies
	D1	D2	D3	D4	D5	D6	D7	D8		
57	X	X	-	1,766		13		-	1,779	4
58	X	X	-	-				-	-	2
59		X	-	-				-	-	1
60	X	X	-	-				-	-	2
61			-	-				-	-	-
62		X	192	-				-	192	2
63			-	-				-	-	-
64			-	-				-	-	-
65	X	X	-	-				-	-	2
66		X	241	313	X	X		-	554	5
67	X	X	-	-				-	-	2
68			-	-				-	-	-
69			-	-				-	-	-
70			-	69	X			-	69	2
71		X	540	-				-	540	2
72			-	-				-	-	-
73	X		-	-				-	-	1
74		X	-	-				-	-	1
75			419	-				-	419	1
76		X	-	-				-	-	1
77			-	-				-	-	-
78	X		-	-				-	-	1
79			-	2,399	X			-	2,399	2
80	X	X	-	-				-	-	2
81	X	X	-	-				-	-	2
82	X		-	-				-	-	1
83	X	X	-	-				-	-	2
84			395	-				-	395	1
85		X	-	-				-	-	1
86			-	-				-	-	-
87			-	-				-	-	-
88			-	-				-	-	-
89		X	-	-				-	-	1
90	X	X	-	2,151	X			-	2,151	4
91	X	X	201	-				-	201	3
92	X	X	-	-				-	-	2
93			-	-				-	-	-
94			-	-				-	-	-
95		X	-	-				-	-	1
96	X	X	-	-				-	-	2

Major Findings	MF 1		MF 2	MF 3	MF 4			MF 5	Total Overpayments	Number of Deficiencies
	D1	D2	D3	D4	D5	D6	D7	D8		
97	X		-	-				-	-	1
98			-	-				-	-	-
99			-	-				-	-	-
100			429	-				-	429	1
<b>Overpayments</b>			\$6,082	\$15,379		\$210			\$21,670	125
<b>Claims in Error</b>	37	41	15	17	9	3	1	2	28	70



**APPENDIX F: SUMMARY OF DEFICIENCIES IN COMPREHENSIVE ASSESSMENTS  
AND PLANS OF CARE PER SAMPLED CLAIM**

**Legend**

<b>Document With Deficiency</b>	<b>Deficiency (D)</b>	<b>Description</b>
Comprehensive assessments	1	Not updated timely, either annually for stable patients or monthly for unstable patients.
	2	Not updated 3 months after the initial assessment.
	3	Did not have the initial assessment conducted within the later of 30 days of admission or 13 dialysis treatments.
	4	Did not contain all the required elements.
Plans of care	5	Not updated timely.
	6	Not signed by the patient and did not document the reason why the signature was not provided.
	7	Not signed by all members of the IDC team.
	8	Did not contain all required elements.

<b>Document Sample Claim</b>	<b>Comprehensive Assessments</b>				<b>Plan of Care</b>				<b>Number of Deficiencies</b>
	<b>D1</b>	<b>D2</b>	<b>D3</b>	<b>D4</b>	<b>D5</b>	<b>D6</b>	<b>D7</b>	<b>D8</b>	
1	X	-	-	-	-	-	-	-	1
2	-	-	-	-	X	-	-	-	1
3	-	-	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-	-	-
8	-	-	-	-	X	-	-	-	1
9	-	-	-	-	-	-	-	-	-
10	-	X	-	-	-	-	-	-	1
11	-	-	-	-	-	-	-	-	-
12	X	-	-	-	-	-	-	-	1
13	X	-	-	-	-	-	-	-	1
14	X	-	-	-	X	-	-	X	3
15	X	-	-	-	X	-	-	-	2
16	-	-	-	-	-	-	-	-	-
17	-	-	-	-	-	X	-	-	1
18	X	-	-	-	-	-	-	-	1
19	-	-	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-	-	-
21	X	-	-	-	X	X	X	-	4

Document Sample Claim	Comprehensive Assessments				Plan of Care				Number of Deficiencies
	D1	D2	D3	D4	D5	D6	D7	D8	
22	-	-	-	-	-	X	-	-	1
23	X	-	-	-	-	-	-	-	1
24	-	-	-	-	X	X	-	-	2
25	X	-	-	-	-	-	-	-	1
26	-	-	-	-	X	X	X	-	3
27	-	-	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-	-	-
29	X	-	-	-	-	-	-	-	1
30	-	-	-	-	X	-	-	-	1
31	X	-	-	-	-	X	-	-	2
32	-	-	-	-	-	-	-	-	-
33	-	-	-	-	-	-	-	-	-
34	X	-	-	-	-	X	X	-	3
35	-	-	-	-	-	X	-	-	1
36	X	-	-	-	X	-	-	-	2
37	-	-	-	-	-	X	-	-	1
38	-	-	-	-	-	-	-	-	-
39	-	-	-	-	-	-	-	-	-
40	X	-	-	-	-	-	-	-	1
41	-	-	X	-	X	-	-	-	2
42	-	-	-	-	-	-	-	-	-
43	-	-	-	-	-	X	-	-	1
44	-	-	-	-	-	-	-	-	-
45	X	-	-	-	-	-	-	-	1
46	-	-	X	-	X	-	-	-	2
47	-	-	-	-	-	-	-	-	-
48	-	-	-	-	-	-	-	-	-
49	-	-	-	-	-	-	-	-	-
50	X	-	-	-	-	-	-	-	1
51	-	-	-	-	-	-	-	-	-
52	-	-	-	-	-	-	-	-	-
53	X	-	-	-	X	-	-	-	2
54	-	-	-	-	-	-	-	-	-
55	X	-	-	-	-	-	-	-	1
56	-	-	-	-	X	-	-	-	1
57	-	X	-	-	X	-	-	-	2
58	X	-	-	-	X	X	-	-	3
59	-	-	-	-	X	-	-	-	1
60	X	X	-	-	X	-	-	-	3
61	-	-	-	-	-	-	-	-	-
62	-	-	-	-	X	-	-	-	1
63	-	-	-	-	-	-	-	-	-

Document Sample Claim	Comprehensive Assessments				Plan of Care				Number of Deficiencies
	D1	D2	D3	D4	D5	D6	D7	D8	
64	-	-	-	-	-	-	-	-	-
65	X	-	-	-	X	X	X	-	4
66	-	-	-	-	-	X	-	-	1
67	X	-	-	-	X	-	-	-	2
68	-	-	-	-	-	-	-	-	-
69	-	-	-	-	-	-	-	-	-
70	-	-	-	-	-	-	-	-	-
71	-	-	-	-	X	-	-	-	1
72	-	-	-	-	-	-	-	-	-
73	X	-	-	-	-	-	-	-	1
74	-	-	-	-	-	X	-	-	1
75	-	-	-	-	-	-	-	-	-
76	-	-	-	-	-	-	-	X	1
77	-	-	-	-	-	-	-	-	-
78	X	-	X	-	-	-	-	-	2
79	-	-	-	-	-	-	-	-	-
80	X	-	-	-	-	-	-	X	2
81	X	-	-	-	-	-	X	-	2
82	X	-	-	-	-	-	-	-	1
83	X	-	-	-	X	-	-	-	2
84	-	-	-	-	-	-	-	-	-
85	-	-	-	-	-	X	-	-	1
86	-	-	-	-	-	-	-	-	-
87	-	-	-	-	-	-	-	-	-
88	-	-	-	-	-	-	-	-	-
89	-	-	-	-	-	X	-	-	1
90	X	-	-	-	-	X	-	-	2
91	X	-	-	-	-	X	-	-	2
92	X	-	-	-	X	-	-	-	2
93	-	-	-	-	-	-	-	-	-
94	-	-	-	-	-	-	-	-	-
95	-	-	-	-	-	X	-	-	1
96	-	-	-	X	-	-	X	-	2
97	X	-	-	X	-	-	-	-	2
98	-	-	-	-	-	-	-	-	-
99	-	-	-	-	-	-	-	-	-
100	-	-	-	-	-	-	-	-	-
<b>Claims in Error</b>	32	3	3	2	23	19	6	3	91

## APPENDIX G: DIALYSIS CLINIC, INC., COMMENTS <sup>106</sup>

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June 7, 2022

VIA FEDEX OVERNIGHT DELIVERY AND ELECTRONIC MAIL

Sheri L. Fulcher  
Regional Inspector General for Audit Services  
U.S. Department of Health & Human Services  
Office of Inspector General  
Office of Audit Services, Region V  
233 North Michigan Ave., Suite 1360  
Chicago, IL 60601

Re: **Dialysis Clinic, Inc.; Response to Audit Report A-05-20-00010**

Dear Ms. Fulcher:

Dialysis Clinic, Inc. (“**DCI**”), through its counsel Bradley Arant Boult Cummings LLP, submits this letter in response to the draft audit report (A-05-20-00010) prepared by the U.S. Department of Health and Human Services (“**HHS**”), Office of Inspector General (“**OIG**”), entitled *Medicare Dialysis Services Provider Compliance Audit: Dialysis Clinic, Inc.* (the “**Draft Report**”), dated April 6, 2022. DCI appreciates the opportunity to submit these comments on the Draft Report. As set forth in further detail below, DCI respectfully objects to both the methodological techniques and the substantive standards applied by OIG in the Draft Report.

Overall, we believe the Draft Report applies inappropriate payment standards and reflects a misunderstanding of the clinical and financial realities of the dialysis industry, particularly those facing nonprofit companies such as DCI. The Draft Report, if finalized in its current form, could result in significant, undue financial harm to DCI and have far-reaching consequences on the delivery of patient care across the dialysis industry as a whole. If finalized in its current form, the Draft Report will have significant policy effects that are not—and have never been—intended by HHS or the Centers for Medicare & Medicaid Services (“**CMS**”).

### **I. Introduction**

DCI began providing dialysis treatments to patients with end-stage renal disease (“**ESRD**”) in 1971 and has grown over the past half-century to become the largest nonprofit dialysis provider in the country. From the beginning, DCI has embraced its nonprofit mission and has devoted its resources toward improving the lives of people living with kidney disease through patient care, including dialysis and transplantation, research, education, and patient-centered innovation in the field, as well as initiatives to help those with chronic kidney disease prevent or delay the need for dialysis. DCI’s service to indigent ESRD patients predates even that of Medicare, which formally established its own ESRD program in 1973.

Today, DCI operates 258 outpatient dialysis clinics in furtherance of its nonprofit mission— together serving over 14,000 patients in 29 states. Each of DCI’s dialysis clinics is separately certified by the Medicare program with a unique provider number, but over 240 of those clinics operate under one large

<sup>106</sup> The deleted text has been redacted because it is personally identifiable information.

corporate tent, as a single legal entity<sup>1</sup> holding a single tax identification number.<sup>2</sup> This organizational structure stands in contrast to most other large provider organizations, including other dialysis and kidney care providers, in which numerous subsidiary entities own and operate the individual clinics. While most regional and national healthcare providers organize into multiple local subsidiary entities for taxation and other reasons, DCI's legal structure remains mostly under one nonprofit entity that exists for the benefit of the public at large and its charitable purposes.

As mentioned, this diverse collection of nonprofit, patient-focused dialysis clinics has been able to successfully operate under the auspices of DCI for over 50 years. Although DCI maintains a number of enterprise-wide clinical and business functions, individual facility operations and clinical practices are ultimately very local matters. DCI's clinics are divided among 51 geographically-bounded business units ("**Local Business Units**"), each of which is managed by its own area operations director. Each Local Business Unit, in turn, comprises multiple dialysis clinics which may have different medical directors responsible for the delivery of patient care and outcomes at the clinics in accordance with 42 C.F.R. § 494.150.<sup>3</sup> Depending on the number of clinics in a given area, a Local Business Unit may cover a portion of a city, an entire city/metropolitan area, or—rarely—an entire state. While DCI does maintain certain enterprise-wide compliance and other policies, the clinics are empowered to modify and tailor their policies and practices to best suit the individual needs of the communities they serve. Although there are sometimes similarities spanning clinical practices, operations, and policies in a given Local Business Unit, there can still be substantially different approaches among the clinics within such Local Business Unit because each clinic has its own governing body, as required by 42 C.F.R. § 494.180. Each clinic may also have a different medical director and different physicians on its medical staff, as well as nurse managers and nursing/clinical staff who are unique to each clinic.<sup>4</sup> Each clinic's governing body has "full legal authority and responsibility for the governance and operation of the facility" and must "adopt[] and enforce[] rules and regulations" relating to such operations.<sup>5</sup> Consequently, the governing body of each clinic may craft unique policies and programs, whether based on local preferences or unique state law requirements.

As described in Section II, the Draft Report does not accurately take into account the nature of DCI's corporate structure and places an undue emphasis on its tax identification number, as opposed to the unique provider number and Medicare certification of each clinic tasked with (1) compliance with Medicare ESRD conditions for coverage ("**CfCs**") at the clinic level (not at the legal entity level) and (2) the day-to-day claims submission that is ultimately the subject of the Draft Report.

The Draft Report summarizes OIG's audit of 100 claims/beneficiary months submitted by DCI in calendar year 2018 (the "**Audit Period**")—a year in which over 112,000 claims were submitted by the 242 clinics included in OIG's sample frame. The Draft Report identified five (5) "Findings." DCI has reviewed the Draft Report and its Findings, and while DCI responds to each Finding below in turn, DCI strongly

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<sup>1</sup> Dialysis Clinic, Inc., a Tennessee nonprofit corporation.

<sup>2</sup> [REDACTED]

<sup>3</sup> In some cases, a single physician practice will supply each physician who serves as a medical director for the respective clinics in a given Local Business Unit; in others, different physician practices provide medical director services for different clinics within a single Local Business Unit.

<sup>4</sup> Even where there are medical director agreements under which a practice may provide medical director services for multiple clinics in an area, it does not have to be—and often is not—the same physician providing the medical director services across all those clinics. It is also worth noting that the physicians actively practicing in those clinics ultimately set the tone for how care is to be provided, and such physicians may or may not be affiliated with the same practice.

<sup>5</sup> 42 C.F.R. § 494.180.

disagrees with the Draft Report's Findings as a whole. As described in the sections that follow, we believe the methodological and substantive deficiencies of the Draft Report make the Findings largely invalid.<sup>6</sup> DCI also strongly disputes those Findings that do not have a payment impact, *e.g.*, Findings 1 and 5 (as discussed in Sections III and VII, respectively). With respect to Finding 2 ("Dialysis Treatments Not Completed") and Finding 3 ("Dialysis Services Not Documented"), DCI disputes the validity of the financial determinations in the Draft Report and believes purported overpayments identified by OIG to be unsubstantiated based on the medical record, unsupported by the pertinent guidance, or both. As discussed in Sections IV and V, we have especially serious concerns about the effects that Findings 2 and 3 would have not only on DCI but also, more generally, on all Medicare-participating dialysis providers and the hundreds of thousands of Americans living with ESRD who depend on them.

## **II. The Draft Report's Subject Matter and Methodological Flaws**

Before responding to each of OIG's findings, we describe two fundamental flaws in OIG's audit that call into doubt each of OIG's specific findings and, indeed, the Draft Report in general. First, DCI respectfully submits that the Draft Report reflects significant misunderstandings about the unique nature of chronic dialysis treatment as distinguished from most other Medicare services. Second, as described in previous conversations and correspondence with OIG, DCI believes the extrapolation methodology employed by OIG to be fundamentally flawed. While either of these flaws alone could call into question the reliability of OIG's audit findings, taken together, these issues undermine the validity of the audit as a whole.

### **a. OIG's Audit Does Not Properly Take into Account the Nature of Dialysis Services or Patients**

OIG's draft audit report follows the structure of prior audits of dialysis service providers, in which the standards employed in audits of Medicare Part B fee-for-service claims were largely transposed to dialysis treatments. ESRD, though, is a chronic condition with bundled payment that is much more similar to Part A hospice services, in which the entirety of the medical record is reviewed by auditors. Hemodialysis is typically performed three times per week (156 times per year). Information relevant to a patient's condition and course of treatment is contained in a voluminous medical record compiled over the course of many chronic treatment sessions. The failure to look at the long-term data which forms the basis of medical decision-making by nephrologists and other providers involved in delivering dialysis treatments is inconsistent with widely accepted clinical and operational practices.

We note also that many of the deficiencies cited by OIG—particularly those falling under Findings 2, 3, and 4—may penalize providers who disproportionately treat the most vulnerable patients within the ESRD population. This result runs contrary to HHS's aim of resolving fundamental disparities caused by social determinants of health.<sup>7</sup> For instance, penalizing dialysis providers based on insufficiencies in

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<sup>6</sup> As noted in the Draft Report, DCI provided OIG with an informational packet in February 2021 detailing, among other things, the internal controls DCI has to ensure clinics comply with Medicare requirements (the "**Supplemental Information Packet**"). Although the body of this letter predominately responds to the substantive standards applied by OIG, unless otherwise noted, we incorporate by reference the materials supplied in the Supplemental Information Packet, including the fulsome descriptions of DCI's internal controls and any claims-specific documentation.

<sup>7</sup> *See, e.g.*, CMS.gov, "CMS Takes Decisive Steps to Reduce Health Care Disparities Among Patient with Chronic Kidney Disease and End-Stage Renal Disease" (Oct. 29, 2021) (describing the care disparities that persist along racial, ethnic, and socioeconomic lines and the Biden administration's efforts to curb those disparities in pursuit of

patient-generated documentation would tilt against providers who treat populations who are less educated or who otherwise lack the competency or resources necessary to create, maintain, and deliver written records in a consistent and timely manner.<sup>8</sup> In other words, reliance on patient-generated documentation inherently disadvantages providers who treat poorer and less educated populations. Such patient-generated documentation is at the heart of Findings 3 and 4.

#### **b. Enterprise-Wide Extrapolation Is Inappropriate**

On or around November 7, 2019, DCI was notified by OIG of its intention to conduct an audit of DCI's Medicare Part B claims. Similar to other dialysis services provider audits, the audit reviews a sample of 100 claims. Unlike those other audits, the 100 claims were drawn from 83 unique dialysis clinics falling under 42 Local Business Units and located in 21 states. Despite the vast demographic, geographic, organizational, and clinical differences among the clinics within the sample, OIG has nevertheless extrapolated the alleged value of financial errors in the 100-claim sample (\$30,097)—not just to all claims submitted by the 83 dialysis facilities covered by the sample—but to all claims submitted by DCI's 242 dialysis clinics during the Audit Period (112,192 claims with payments totaling \$276,427,841).<sup>9</sup> That is, the findings from what was primarily one monthly claim from each of roughly one-third of DCI's dialysis clinics—representing well under 0.1% of the total payments at issue—have been generalized to all of the claims submitted by all of the company's dialysis clinics.

DCI engaged Michael P. Salve, Ph.D. of FTI Consulting, an applied economist who is qualified as an expert statistician, to evaluate the OIG's sampling methodology, extrapolation calculations, and findings in the Draft Report. We have enclosed with this letter copies of Dr. Salve's curriculum vitae and expert report analyzing the Draft Report (the "Expert Report," enclosed as Exhibit A).<sup>10</sup>

As set forth in the Expert Report, Dr. Salve concluded that the OIG's "extrapolation method for the alleged overpayments is unreliable and statistically invalid because it is based on a flawed sample design." Dr. Salve further concluded that because the OIG "failed to draw a statistically valid sample, it is inappropriate to extrapolate the results from the sample to the overall universe of claims."<sup>11</sup>

As described more specifically below and in the Expert Report, OIG's extrapolation is inappropriate from a statistical perspective and runs in direct contradiction of the limited federal guidance on the subject. At a high level, the audit should be focused on the provider, not the entire enterprise—that is, it should be organized by provider number or National Provider Identifier, not tax identification number. Alternatively, if the focus is on the entire enterprise, the sample must be representative of it. It is, however, inappropriate to generalize the results of a miniscule sample of claims covering only a small portion of the company's clinics to the entirety of its operations, and it is fundamentally unfair to penalize a company based on its organizational structure.

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"better outcomes, greater autonomy and better quality of life"), available at <https://www.cms.gov/newsroom/press-releases/cms-takes-decisive-steps-reduce-health-care-disparities-among-patients-chronic-kidney-disease-and>.

<sup>8</sup> It is worth emphasizing here that DCI's clinics are established with an eye toward the needs of the local community, and such needs are often greatest in the most socioeconomically disadvantaged communities.

<sup>9</sup> We understand that OIG auditors generally calculate the lower limit of a two-sided 90 percent confidence interval and use such limit when estimating overpayments.

<sup>10</sup> Michael P. Salve, Ph.D., FTI Consulting, *Office of Inspector General, Office of Audit Services ("OAS"), Draft Report Regarding Dialysis Clinic, Inc.: Expert Report* (June 7, 2022).

<sup>11</sup> *Id.* ¶ 9, at 4.

First, attributing the findings of 100 claims to more than 240 unique providers calls into question the accuracy of OIG’s findings and ultimately means that OIG’s recommendations will not be tailored to the issues they purport to address. DCI owned and operated 242 dialysis clinics during the Audit Period.<sup>12</sup> While under common ownership, the clinics, located from Maine to California, were separate and distinct healthcare facilities. Each was separately enrolled in the Medicare program; subject to separate licensure, certification, and surveying; and under the jurisdiction of different Medicare Administrative Contractors (“MACs”). Each clinic within the sampling frame served distinct patient populations, and each was subject to the oversight and clinical direction of different local personnel (*e.g.*, area operations directors, medical directors, governing bodies, nursing staff). Projecting the findings from a review of 100 claims from roughly one-third of these clinics to all 112,192 of the claims submitted by all of the company’s clinics, simply because they were housed within the same legal entity, results in an unrepresentative sample. It also creates real risk that OIG’s recommendations will be meaningless—*i.e.*, that the audit will fail to accurately diagnose problems and offer solutions. Simply put, for the audit results to be generalizable, the sample must be representative of the population. The correct unit of measurement is the individual provider, not the legal entity that happens to hold the assets and operations of that provider and many others.

In sum, as Dr. Salve states in the Expert Report, “OAS employed a deficient sampling methodology that renders any overpayment calculations unable to be reliably extrapolated to its population of claims,” and the “sampling methodology fails to consider geography and, as a result, leads to a sample that is unrepresentative of the population with respect to geography.”<sup>13</sup> Noting the vast geographic spread of DCI’s footprint and the significant operational differences among DCI’s Local Business Units, the Expert Report emphasizes that the Draft Report “failed to control for these differences across business units and states and instead extrapolates a sample of 100 claims that is unrepresentative with respect to geography” and concludes that “[a]ltogether, the sample design is deficient, and the extrapolation results are unreliable because the sample does not reflect the population as a whole.”<sup>14</sup>

Setting aside the specific substantive concerns raised in Exhibit A, the sample design employed in the Draft Report has been flawed from the beginning. Drawing samples from more than one provider is inconsistent with generally accepted auditing standards, including those used by CMS. The first step in conducting statistical sampling is to identify the provider or supplier that submitted the claims at issue. Indeed, CMS instructions to contractors regarding the use of statistical sampling in their reviews and estimations of overpayment cite “[i]dentifying the provider/supplier” as the first “major step[] in conducting statistical sampling.”<sup>15</sup> When defining the universe of claims, CMS instructions emphasize that the unit of measurement is the provider or supplier, not the legal entity or its tax identification number.<sup>16</sup> While CMS guidelines do not bind OIG, the foregoing principles are fundamental to the use of statistical sampling in any medical claims review. Moreover, the government frequently cites to the Medicare Program Integrity Manual for the proposition that the validity of a “properly executed” sample design cannot be questioned.<sup>17</sup>

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<sup>12</sup> DCI affiliate entities owned 14 additional dialysis clinics during the Audit Period, but claims submitted by those clinics were not included in the sample frame.

<sup>13</sup> *Id.* at 1 (internal footnotes omitted).

<sup>14</sup> *Id.* at 1-2 (internal footnotes omitted).

<sup>15</sup> *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 8, § 8.4.1.3.

<sup>16</sup> *See id.* at § 8.4.3.2.1(B) (stating that, for Part B claims, “[t]he universe shall consist of all fully and partially paid claims submitted by the provider/supplier for the period selected for review and for the sampling units to be reviewed”) (emphasis added).

<sup>17</sup> *See, e.g.*, Brief of Appellees at 31, *Palm Valley Health Care, Inc. v. Azar*, 947 F.3d 321 (5th Cir. 2020) (“The . . . steps of the MPIM guidelines are: (1) select the provider or supplier . . . Thus, based on the sampling methodology, supporting sampling documentation, and the testimony at the hearing, the Council properly concluded that the



That said, where the requirements for sample design—including provider selection, as here—are not followed, courts are more willing to strike down extrapolation methodologies because “[f]ailure to follow [statistical procedures and safeguards in the Medicare Program Integrity Manual] is indicative that the statistical analysis may not be valid.”<sup>18</sup>

Finally, conducting a nationwide audit of claims for Medicare dialysis services furnished by a single organization represents a significant departure from OIG’s historical practices. Previous dialysis providers subject to OIG audits have been owned by national dialysis companies, but all of the audits have focused upon either a single dialysis clinic or a small number of dialysis clinics with like characteristics, and none have been nationwide in scope.<sup>19</sup> As applied to DCI, this approach would be consistent with an audit of *one* of its clinics or Local Business Units. While OIG has on occasion focused targeted audit criteria on multiple provider facilities when addressing a specific compliance concern (*e.g.*, the administration of Epogen), even in those targeted reviews, OIG has limited its samples geographically.<sup>20</sup>

### III. Response to Draft Report Finding 1: “Comprehensive Assessments and Plans of Care Did Not Meet Medicare Requirements”

OIG’s first major finding states that 57 claims in the sample had documentation errors falling into one of two subcategories: (1) errors in patient plans of care; and (2) errors in comprehensive assessments (“**Finding 1**”).<sup>21</sup> Although there was no financial impact resulting from Finding 1, DCI’s clinics take the proper documentation for plans of care and comprehensive assessments seriously.

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sampling resulted in a ‘probability sample,’ giving rise to the presumption that the projected overpayment amount was valid.”); *see also Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 8, § 8.4.2 (“If a particular probability sample design is properly executed, *i.e.*, defining the universe, the frame, the sampling units, using proper randomization, accurately measuring the variables of interest, and using the correct formulas for estimation, then assertions that the sample or that the resulting estimates are ‘not statistically valid’ cannot legitimately be made. In other words, a probability sample and its results are always ‘valid.’”).

<sup>18</sup> *See, e.g., Central Louisiana Home Health Care, L.L.C. v. Price*, 2018 WL 7888523 at \*19 (W.D. La. Dec. 28, 2018) (“The MPIM requirements are the safeguards that ensure the validity of a statistical analysis . . . [A]dherence to the safeguard procedures in the MPIM becomes of particular importance in according a presumption of correctness and validity to the statistical analysis. *Failure to follow those procedures is indicative that the statistical analysis may not be valid.*”) (emphasis added).

<sup>19</sup> *See, e.g., Medicare Dialysis Services Provider Compliance Audit: Bio-Medical Applications of Arecibo, Inc.*, OIG Report No. A-02-17-01016 (Mar. 2020) (covering four dialysis clinics located in Puerto Rico operated by an affiliate of Fresenius Medical Care); *Compliance Review of Woburn Dialysis*, OIG Report No. A-01-12-00516 (Apr. 2014) (covering a single dialysis clinic located in Massachusetts operated by an affiliate of DaVita); *Compliance Review of Lowell General Hospital’s Methuen Dialysis Facility*, OIG Report No. A-01-12-00517 (Feb. 2014) (covering a single dialysis facility located in Massachusetts operated by Lowell General Hospital). *Cf. Dialysis Services Provided by Atlantis Health Care Group of Puerto Rico, Inc., Did Not Comply with Medicare Requirements Intended to Ensure the Quality of Care Provided to Medicare Beneficiaries*, OIG Report No. A-02-16-01009 (Dec. 2018) (reviewing claims from 17 dialysis clinics operated by the audited party in Puerto Rico, all of which were operated under the oversight of a single MAC; subject to uniform, company-wide compliance programming; and because of the limited geographic scope, likely had significant overlap in personnel and patient demographics).

<sup>20</sup> Such was the case in an audit involving certain of DCI’s clinics in the greater Boston area nearly 20 years ago. *See Review of Internal Control Procedures at Dialysis Clinic, Inc. Facilities Located at Boston and Somerville, Massachusetts for the Administration of Epogen for Calendar Year 1999*, OIG Report No. A-01-01-00544 (Jun. 2002).

<sup>21</sup> Draft Report at 6-7 (internal citations omitted).

Each dialysis patient is assigned an interdisciplinary team responsible for providing each patient with an individualized, comprehensive assessment of their needs. The comprehensive assessment is used to develop the accompanying plan of care. The plan of care reflects the comprehensive assessment and is signed by all members of the interdisciplinary team and the beneficiary. Comprehensive assessments and plans of care are conducted annually for stable patients and at least monthly for unstable patients.

DCI's clinics have robust internal controls regarding plans of care and comprehensive assessments, and staff are periodically trained on the required components and processes for plans of care and comprehensive assessments. Moreover, clinics use electronic auditing, tracking, and coordination tools to ensure timely completion and fulfillment of all required components. Nevertheless, consistent with OIG's recommendations, DCI and its clinics are constantly refining, enhancing, and updating best practices and compliance processes. Accordingly, DCI is working to ensure that clinics complete and update patient assessments and plans of care timely based on the completion date of the last assessment; to refresh written policies and procedures to secure staff availability during extended leave or vacancies; and to ensure clinical staff obtain all required elements and signatures.

#### a. Claims-Specific Responses to Finding 1

In addition to the above general comments, which DCI believes are applicable to all claims OIG has identified as having this deficiency, following are DCI's specific responses to certain individual sample claims.

- i. **Sample 10:** Sample 10 is cited by OIG for Deficiency 2, namely that the comprehensive assessment was "not updated 3 months after the initial assessment." OIG's finding is incorrect and is not supported by the medical record. A comprehensive assessment for Sample 10 was updated in compliance with the three-month follow-up assessments and care plan requirements through DCI's electronic information system's care plan programming, which schedules the due date for assessments and care plan updates in three-month increments measured from the initial care plan due date, including assessments to be completed prior to the plan of care.
- ii. **Sample 12:** An annual/stable care plan was completed on March 29, 2017, and the next care plan was an annual/stable care plan completed on March 28, 2018. The next annual care plan would have been due on March 29, 2018, but it was completed one day prior to the due date.
- iii. **Sample 13:** An annual/stable care plan was completed on January 4, 2017, and the next care plan was an annual/stable care plan completed on January 3, 2018. The next annual care plan would have been due on January 4, 2018, but it was completed one day prior to the due date.
- iv. **Sample 25:** An annual/stable care plan was completed on January 26, 2017, and the next care plan was an annual/stable care plan completed on February 22, 2018. The patient was in the hospital for 14 days from January 3, 2018 through February 2, 2018, and clinic completed the care plan 9 days after patient's return to the clinic.
- v. **Sample 30:** With regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555

(Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 30, the following alerts were triggered, evidencing compliance with required elements as to this sample: modality education alert (optional for care plan); high probability of depressive disorder: addressed on care plan; no secondary insurance (optional for care plan). Social work notes support attempts to obtain financial assistance form or secondary insurance. Data also exists to support alerts not otherwise being triggered, including the following: Kt/V > 1.3 on monthly labs (1.61); AVG; transplant active; retired due to disability; fall risk score < 10 (5); ambulatory without assistive devices.

Separately, it should be noted that patient signature was obtained and submitted with care plans (January 5, 2017 and June 27, 2018).

- vi. **Sample 36:** An annual/stable care plan was completed on August 11, 2016, and the next care plan was an annual/stable care plan completed on July 28, 2017. The next annual care plan would have been due on August 11, 2017, but it was completed 13 days prior to the due date for the May 2018 audited period.

Separately, with regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555 (Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 36, the following alerts were triggered, evidencing compliance with required elements as to this sample: Fall Risk: Addressed on care plan; Impaired Hearing (optional for care plan). Data also exists to support alerts not otherwise being triggered, including the following: Kt/V > 1.3 on monthly labs (1.31); unsuitable for transplant – denies interest; modality education provided; AVF; PHQ < 10 (2); fully insured; retired; coping with disease; access to food; does not have limited nutrition knowledge.

- vii. **Sample 40:** An annual/stable care plan was completed on January 19, 2017, and the next care plan was an annual/stable care plan completed on January 17, 2018. The next annual care plan would have been due on January 19, 2018, but it was completed two days prior to the due date.
- viii. **Sample 43:** With regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555 (Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 43, the following alerts were triggered, evidencing compliance with required elements as to this sample: Fall Risk: Addressed on care plan; Limited

Mobility (optional for care plan); Patient doesn't follow treatment plan; Addressed on care plan; Patient is not coping with disease (optional for care plan). Data also exists to support alerts not otherwise being triggered, including the following: employed full time; transplant referral in progress; access to food; does not have limited nutrition knowledge; Kt/V > 1.3 for only one month.

- ix. **Sample 46:** With regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555 (Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 46, the following alerts were triggered, evidencing compliance with required elements as to this sample: Patient Requires Education about Transplant: Addressed on care plan; Modality Education: Addressed on Care plan; Patient has CVC with no maturing access: Addressed on care plan. Data also exists to support other alerts not being triggered, including the following: Kt/V > 1.3 (1.53); fall risk < 10 (4); PHQ < 10 (0); vocational rehab not triggered, patient employment not entered on initial assessment; fully insured; coping with disease; access to food; does not have limited nutrition knowledge.

- x. **Sample 50:** An annual/stable care plan was completed on June 29, 2017, and the next care plan was an annual/stable care plan completed on June 22, 2018. The next annual care plan would have been due on June 29, 2018, but it was completed 7 days prior to due date.
- xi. **Sample 53:** The plan of care was updated timely. An initial/stable care plan was completed on February 22, 2018. The next care plan completed was an unstable care plan dated April 9, 2018, which was quickly followed by a completed stable care plan on April 19, 2018. The next care plan to deem stable would be due by May 9, 2018, which was completed ten days prior to due date.

Additionally, the initial comprehensive assessment was conducted within 30 days of admission or 13 dialysis treatments. The first treatment date was January 17, 2018, but Sample 53 did not have a 13<sup>th</sup> dialysis treatment until March 2, 2018. As a result, the comprehensive assessment was in compliance because the initial assessments/plan of care were completed on February 22, 2018, prior to the patient's 13<sup>th</sup> dialysis treatment.

- xii. **Sample 60:** The initial/stable plan of care was completed on March 12, 2018, and next stable plan of care was completed on July 23, 2018.
- xiii. **Sample 73:** An annual/stable care plan was completed on July 19, 2016, and the next care plan was a stable care plan completed on July 18, 2017. The next annual care plan would have been due on July 17, 2018, but a note is documented in the care plan application by the care plan owner for July 19, 2017: "physician/ARNP schedule." In addition, there was a current care plan for the April 2018 audited period because a care plan had been completed within one year.
- xiv. **Sample 76:** With regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555

(Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 76, no alerts were triggered, evidencing compliance with required elements as to this sample. Data also exists to support alerts not being triggered, including the following: AVF; transplant referral offered, patient refused; Kt/V > 1.3 (1.52); modality education provided; PHQ < 10 (0); retired (disabled); fully insured; coping with disease; access to food; does not have limited nutrition knowledge.

- xv. **Sample 78:** An initial/stable care plan was completed on September 26, 2018, and the next care plan was an unstable care plan completed on October 24, 2018. For the third care plan, November 24, 2018 fell on a Saturday; therefore, the clinic completed the new care plan the following Monday, November 26, 2018.
- xvi. **Sample 80:** An annual/stable care plan was completed on April 27, 2017, and the next care plan was an annual/stable care plan completed on April 26, 2018. The next annual care plan would have been due on April 27, 2018, but it was completed one day prior to the due date.

Separately, with regard to the required elements for plans of care, DCI's comprehensive assessments used with care plans include assessment of all elements covered in V502 – V515. Specific to care plan sections for V555 (Rehabilitation Status), V562 (Education and Training), V552 (Psychosocial Status), V550 (Vascular Access Monitoring), and V543 (Dialysis Dose), DCI has internal controls to trigger items requiring elevation to the care plan.

For Sample 80, no alerts were triggered, evidencing compliance with required elements as to this sample. Data also exists to support alerts not being triggered, namely, employment full time; fully insured; PHQ < 10 (0); Kt/V > 1.3 (1.62); has LUAVF; fall risk score < 10 (3); permanently inactive and removed from transplant list; coping with disease; access to food; does not have limited nutrition knowledge.

- xvii. **Sample 81:** An annual/stable care plan was completed on December 6, 2016, and the next care plan was a stable care plan completed on December 7, 2017. The next annual care plan would have been due on April 27, 2018, but a note is documented in the care plan application by the care plan owner for December 7, 2017: "MD schedule has changed." In addition, there was a current care plan for the February 2018 audited period because a care plan had been completed within one year.
- xviii. **Sample 96:** The patient's interdisciplinary care plan lacks the signature of licensed clinical social worker ("LCSW") assigned to the patient; however, valid justification for the missing signature is also demonstrated in the medical record, which states, "This assessment was not electronically completed for the following reason: Staff member on leave."

For the same reason, the deficiency cited in the LCSW's assessment is inappropriately applied. Because the LCSW was on leave, the assessment could

not be completed for the care plan by July 27, 2018. Sample 96's assessments otherwise contained all of CMS's required elements outside the LCSW's assessment for transplant and health status. However, the nursing and dietitian assessments have elements of the health habits and safety section, as well as the ability to perform activities of daily living. Moreover, review of Sample 96's care plan dated July 27, 2018 shows that topics discussed with the assigned LCSW—as late as the June 25, 2018 progress note—include transplant, language barrier, and quality of life. In addition, review of the dates after the care plan meeting shows new LCSW progress/care plan notes. Meanwhile, the July 13, 2018 nursing assessment includes an adequacy section with trending of adequacy labs in goal. Although the July adequacy lab had not been collected for monthly July labs at the time the assessment was completed, the dietitian's assessment includes July adequacy result in goal.

- xix. **Sample 97:** An annual/stable care plan was completed on September 18, 2017, and the next care plan was an annual/stable care plan completed on September 17, 2018. The next annual care plan would have been due on September 18, 2018, but it was completed one day prior to the due date.

Separately, the patient's comprehensive assessment contains all elements other than those which, justifiably, were not obtainable. Specifically, the LCSW was unavailable during the applicable time of the assessment, as noted in the medical record, which states, "This assessment was not electronically completed for the following reason: Staff member on leave." Consequently, the LCSW assessment could not be completed for the care plan by September 17, 2018. Sample 96's assessments otherwise contained all of CMS's required elements outside the LCSW's assessment for transplant and health status. However, the nursing and dietitian assessments have elements of the health habits and safety section, as well as the section on the ability to perform activities of daily living. In addition, review of the dates after the care plan meeting shows new LCSW progress/care plan notes.

#### IV. Response to Draft Report Finding 2: "Dialysis Treatments Not Completed"

OIG's second finding suggests that, for 26 claims, "DCI billed for dialysis treatments that were discontinued 10 or more minutes prior to the beneficiary's complete treatment and for which the beneficiary's medical record did not document a valid reason (e.g., a medical emergency when the patient must be rushed to an emergency room) for discontinuing treatment or the beneficiary's refusal of treatment" ("**Finding 2**").<sup>22</sup> As an initial matter, it should be noted that DCI has robust clinical systems, internal controls, and training in place to ensure that each treatment meets its prescribed length and to track the average duration of each patient's treatments over time. Moreover, the patient education program emphasizes the importance of adherence to prescribed treatment time, and DCI's information systems keep track of early terminations so that patterns may be identified. Consistent with OIG's recommendations, DCI continues to reinforce, through training and remediation efforts, its internal controls for documenting the discontinuance of dialysis treatments and for rescheduling any incomplete treatments; in addition, DCI and its clinics continually communicate to beneficiaries the importance of both timely arrival to treatment appointments and faithful adherence to the prescribed duration of those appointments.

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<sup>22</sup> Draft Report at 9 (internal citations omitted).

As discussed more fully below, however, DCI strongly disagrees with Finding 2 for several reasons, including that: (a) early discontinuation of properly ordered services has no material impact on payment, particularly when the patient receives adequate dialysis as measured by Medicare-recognized laboratory values (*i.e.*, the Kt/V formula<sup>23</sup>); and (b) the standard for early discontinuation articulated in the Draft Report is erroneous and in direct contravention of other federal ESRD policies.<sup>24</sup>

**a. Finding 2 Has No Financial Impact**

First, reporting of treatment time *is not* a condition to payment.<sup>25</sup> In other words, *prospective payment is triggered when treatment commences, irrespective of when the treatment ends.*<sup>26</sup> There is no payment consequence for infrequent occasions when a patient’s treatment does not last the prescribed length, since the ESRD prospective payment rate is not dependent upon the time period associated with the actual dialysis treatment itself.<sup>27</sup>

Medicare payment for dialysis treatments under the PPS has been established as a per-dialysis treatment, and the base rate payment does not vary based upon the length of treatment.<sup>28</sup> Costs of providing the treatment are incurred by DCI when treatment is initiated, and the bundled rate accounts for these costs. Here, DCI incurred the full cost of treatment for each of the patients and in all but one instance the patient received adequate dialysis treatment, as measured by Kt/V.<sup>29</sup>

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<sup>23</sup> See, e.g., 85 Fed. Reg. 71398, 71466 (Nov. 9, 2020) (describing Kt/V as a “clinical measure . . . of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume”); *CMS ESRD Measures Manual for the 2022 Performance Period* (version 7.1), § 2.7.7 (stating in pertinent part that the threshold Kt/V measurement for hemodialysis treatments is  $\geq 1.2$ ).

<sup>24</sup> See, e.g., Good Guidance Petition Response 21-01 (Jan. 8, 2021), available at <https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf>.

<sup>25</sup> *Id.* at 3 (“**If CMS wishes to impose mandatory time collection as a condition of Medicare payment in the future, it will only do so after engaging the public in notice-and-comment rulemaking.**”) (emphasis added).

<sup>26</sup> See, e.g., CMS, *The Provider Reimbursement Manual - Part 1*, ch. 27, § 2702.1(A-B) (stating that “[i]f a dialysis treatment is started . . . but the treatment is not completed for some unforeseen, but valid reason . . . the facility is paid on the full composite rate” as long as it is “documented to the intermediary’s satisfaction,” but noting that “[i]f a facility sets up in preparation for a dialysis treatment, *but the treatment is never started*, e.g., the patient never arrives, no payment is made” because “no service has been furnished to a Medicare beneficiary” and “the program is already paying the cost of predialysis services through the facility’s per treatment composite rate.”) (emphasis added). See, *infra*, Section IV.b for further discussion of the applicable standard.

<sup>27</sup> *Id.*; see also 81 Fed. Reg. 77834, 77870 (Nov. 4, 2016) (stating that, in the rare circumstances where a beneficiary receives services in both ESRD facility and hospital settings in a single day—even if one or both treatments are uncompleted—CMS is required to pay for the treatment received in *both* settings “if a dialysis treatment is started, that is, a patient is connected to the machine and a dialyzer and blood lines are used, but the treatment is not completed for some unforeseen, but valid reason, for example, a medical emergency when the patient must be rushed to an emergency room.”).

<sup>28</sup> We note that the ESRD Quality Incentive Program (“QIP”), established pursuant to the Medicare Improvements for Patients and Providers Act (“MIPPA”) of 2008, already financially accounts for any quality-of-care concerns regarding treatment duration through its inclusion of Kt/V measures.

<sup>29</sup> The exception claim here was truly a rare situation: a pregnant ESRD beneficiary undergoing dialysis treatments. Pregnancy makes achieving dialysis adequacy much more difficult, even when the patient completes treatments for the prescribed length. In fact, for pregnant patients, the primary clinical goal of treatment is not to achieve dialysis adequacy, but to cause the least hemodynamic instability possible due to the severe risks that hypotension presents to a fetus.

Although OIG has stated in prior dialysis audit reports that Medicare “does not reimburse dialysis providers for incomplete dialysis treatments,”<sup>30</sup> no such statement was made with respect to this finding in its most recent dialysis audit report.<sup>31</sup>

In addition, even though we believe there is no authority for imposing payment consequences for uncompleted dialysis treatments (particularly those where the patient received adequate dialysis), for some samples, it appears as though OIG has used the inappropriate financial metrics—the recoupment amount should be tied to the actual reimbursement amount for that date instead of the Medicare allowable amount.<sup>32</sup>

#### **b. Finding 2 Misapplies the Standard for Early Discontinuation**

In 2019, the U.S. Supreme Court issued its opinion in *Azar v. Allina Health Services*, which clarified and distinguished the legal principle applicable to federal administrative actions under the Administrative Procedure Act (“APA”) from the legal principle applicable to administrative actions taken in the context of the Medicare program.<sup>33</sup> Specifically, *Allina* stands for the proposition that no “substantive legal standard” may be created or enforced under the Medicare program without first making such substantive legal standard available to the public through notice-and-comment rulemaking.<sup>34</sup> Importantly, the Court reiterated in *Allina* that any rule “affect[ing] a . . . right to payment” is a substantive legal standard.<sup>35</sup> The Supreme Court’s decision in *Allina* applies to the Draft Report because the OIG, through Major Finding 2 (and also Major Finding 3), is attempting to enact a substantive legal standard with payment consequences that does not otherwise exist in the Medicare statute or in any binding regulation.

In January 2021, HHS rescinded CMS Transmittal 10368 (the “Time Transmittal”) which had previously required ESRD facilities to report data on the total number of minutes of a dialysis session for Medicare beneficiaries.<sup>36</sup> As DaVita said in its petition to challenge the transmittal, “the new Time Transmittal would materially expand reporting requirements and create new consequences (non-payment of claims) for failure to meet those requirements.”<sup>37</sup> HHS stated the following in its rescission of the Time Transmittal:<sup>38</sup>

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<sup>30</sup> *Dialysis Services Provided by Atlantis Health Care Group of Puerto Rico, Inc., Did Not Comply with Medicare Requirements Intended to Ensure the Quality of Care Provided to Medicare Beneficiaries*, OIG Report No. A-02-16-01009 at 10 (Dec. 2018).

<sup>31</sup> *Medicare Dialysis Services Provider Compliance Audit: Bio-Medical Applications of Arecibo, Inc.*, OIG Report No. A-02-17-01016 (Mar. 2020).

<sup>32</sup> See Sample 40 (\$265 versus \$207.45).

<sup>33</sup> *Azar v. Allina Health Services*, 587 U.S. \_\_\_, 139 S.Ct. \*1804, \*1814 (2019) (“In the end, all of the available evidence persuades us that the phrase ‘substantive legal standard,’ which appears in § 1395hh(a)(2) and apparently nowhere else in the U.S. Code, cannot bear the same construction as the term ‘substantive rule’ in the APA.”).

<sup>34</sup> See also 42 U.S.C. § 1395hh(a)(2) (requiring notice-and-comment rulemaking for any “rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits”).

<sup>35</sup> *Allina*, 139 S.Ct. at \*1811.

<sup>36</sup> Good Guidance Petition Response 21-01 (Jan. 8, 2021), available at <https://www.hhs.gov/sites/default/files/davita-petition-response-and-exhibit.pdf>.

<sup>37</sup> *Id.*, Exhibit A at 2.

<sup>38</sup> *Id.* at 1-2.



- “CMS announced this requirement solely through sub-regulatory guidance. . . These documents are not interpretive rules; instead they impose binding new obligations that are not reflected in duly enacted statutes or regulations lawfully promulgated under them . . .”
- “To the extent this regulation purports to authorize the Secretary, through sub-regulatory issuances, to require *the submission of additional data or other information not listed in the regulation*, it is invalid, as this would be an unlawful end-run around the notice-and-comment requirements of the APA and Social Security Act Section 1871.” (emphasis added).

In other words, on the very issue of dialysis treatment time, HHS itself concluded it could not enact a requirement through sub-regulatory guidance because it was “an unlawful end-run.” As discussed below, the Draft Report would do exactly what the HHS conceded last year was unlawful: imposing a binding new legal standard on the issue of dialysis treatment time that could affect payment to dialysis facilities.

The Social Security Act provides for the payment of Medicare Part A and Part B services that are “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”<sup>39</sup> The basic Medicare payment conditions cited under Finding 2 in the Draft Report (42 C.F.R. § 424.5(a)(6)) include not only “sufficient information to determine whether payment is due and the amount of payment” but also requirements related to the types of services covered, beneficiaries eligible for services, and other conditions.

Neither the statute nor the Code of Federal Regulations includes any requirement suggesting that specific documentation describing a reason for early discontinuation of a dialysis treatment has an effect on the amount of payment made to a dialysis facility, let alone whether payment may be denied entirely on this basis. As noted above, the binding Medicare regulation covering documentation in this case requires only that “sufficient information to determine whether payment is due and the amount of payment.” That regulation does not list specific documentation of any kind, including documenting the basis for discontinuing dialysis treatments early.

The ESRD PPS treatment rate is the same regardless of treatment length, and CMS’s payment obligation is triggered upon initiation of the treatment. Under the ESRD PPS bundled per-treatment payment methodology, CMS recognizes that dialysis facilities have already incurred the costs of a treatment *upon the commencement* of such treatment, and therefore pays claims without adjustment based on treatment time.

While no binding legal authority discusses uncompleted dialysis treatments, CMS does comment on uncompleted treatments (see footnote 42 to the Draft Report), in the form of non-binding sub-regulatory guidance (two locations in Medicare manuals, and one reference in Federal Register commentary). The three sources of authority cited by the OIG in footnote 42 are substantially similar. The Medicare Claims Processing Manual, chapter 8, § 10.2 states:

“A dialysis treatment is started, when a patient is connected to the machine and a dialyzer and bloodlines are used. However, if the [*sic*] is not completed for some unforeseen, but valid reason such as a medical emergency when the patient must be rushed to an emergency room, the facility

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<sup>39</sup> Social Security Act § 1862(a)(1)(A)(42 U.S.C. § 1395y(a)(1)(A).

is paid based on the full Prospective Payment System (PPS) base rate. This is a rare occurrence and must be fully documented to the A/B MAC (A)'s satisfaction."<sup>40</sup>

Notably, this authority: (1) allows for full payment of uncompleted dialysis treatments when documented "to the A/B MAC (A)'s satisfaction," without any payment adjustment, and (2) is completely silent on any payment consequences where the dialysis facility's documentation does not meet the undefined "satisfaction" standards of MACs. Of further note, there is no authority, binding or non-binding, to support denying payments *in their entirety* (as opposed to a payment adjustment) for treatments discontinued more than ten minutes prior to the end of the prescribed treatment length. As a result, the ten-minute standard applied in the Draft Report appears to have been arbitrarily selected—without regard to the "valid reason[s]" that animate the day-to-day clinical decision-making and medical judgment of dialysis practitioners, or choices exercised by patients, as discussed in more detail below.

We note that other CMS sub-regulatory guidance in the Medicare Program Integrity Manual would support fully paying claims discontinued early under certain circumstances. As noted above, the Social Security Act authorizes payment for "reasonable and necessary services." The Medicare Program Integrity Manual (chapter 13, § 13.5.4) states:

"Contractors shall determine if evidence exist [*sic*] to consider an item or service to be reasonable and necessary if the contractor determines that the service is:

- Safe and effective;
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
- *Appropriate, including the duration and frequency* that is considered appropriate for the item or service, in terms of whether it is:
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition* or to improve the function of a malformed body member;
  - Furnished in a setting appropriate to the patient's medical needs and condition;
  - Ordered and furnished by qualified personnel;
  - One that meets, but does not exceed, the patient's medical need; and
  - At least as beneficial as an existing and available medically appropriate alternative." (emphasis added).

We draw attention to this provision of the Medicare Program Integrity Manual because it demonstrates that CMS allows for coverage of services of various duration and frequency if furnished in accordance with accepted medical practice. In all but one claim<sup>41</sup> cited under Finding 2 in the Draft Report, the beneficiaries' laboratory values for determining the adequacy of the dialysis treatment (known as Kt/V) show that the uncompleted treatments resulted in the patient receiving adequate dialysis for that month.

When the patients' medical records are viewed in their entirety, the claims included in Finding 2 meet the medical necessity standards set forth in the Medicare statute and include documentation "sufficient

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<sup>40</sup> We would also note that, in the paragraph immediately following Section 10.2 (namely Section 10.3), CMS provides clear guidance on when payment is not due.

<sup>41</sup> *Supra* note 29.

[] to determine whether payment is due and the amount of payment” as required under the binding documentation requirements at 42 C.F.R. § 424.5(a)(6). Only in non-binding sub-regulatory guidance (see footnote 42 of the Draft Report) does the Draft Report find any discussion of specific documentation for discontinued dialysis treatment. And, as discussed above, this guidance does *not* state that dialysis treatment payments are reduced, let alone denied entirely, based on the absence of specific documentation. In fact, the only directive to providers with regard to documentation of such early termination events states that the reason for the uncompleted treatment merely must be “documented to the [private Medicare Administrative Contractor’s] satisfaction.” In each claim for which Finding 2 has been cited as a deficiency by OIG, DCI complied with that directive—as demonstrated by the decision of the applicable MAC to approve each claim for payment.

On the other hand, treating the sub-regulatory guidance cited in footnote 42 of the Draft Report as authoritative requires ignoring the above-cited Medicare Program Integrity Manual provisions. We do not see a basis for reliance on the guidance cited in footnote 42, particularly when CMS has separately published guidance of equal weight (the Medicare Program Integrity Manual provisions above) that leads to the opposite of the OIG’s conclusions.

In addition to the concerns we have with the legal basis for Finding 2, denying payment for uncompleted treatments based on an inflexible specific documentation requirement would run contrary to broader Medicare goals at the heart of the ESRD benefit. As the OIG noted in the Draft Report, the ESRD CfCs protect patients’ right to refuse or discontinue treatment (42 C.F.R. § 494.70(a)(5)) and require dialysis facilities to inform patients of these rights. Another ESRD CfC requires dialysis facilities: “to assist the patient in achieving and sustaining an appropriate psychosocial status as measured by a standardized mental and physical assessment tool chosen by the social worker, at regular intervals, or more frequently on an as-needed basis.”<sup>42</sup>

As noted above, hemodialysis is typically performed three times per week (156 times per year) and can take up to six hours of a beneficiary’s time on a treatment day (including travel and preparation time). As noted in the guidance cited in footnote 42 of the Draft Report, patients sometimes must end dialysis treatments early for clinical reasons. Other patients who discontinue treatments early often do so because they have jobs or other important activities to attend, or because they rely on scheduled transportation from caregivers, friends or sources of public transit that necessitates early discontinuation. From a clinical perspective, patients who remain active in the labor force or engaged in other activities (*e.g.* volunteer work, continuing education), particularly those with chronic conditions, may realize physical and psychological benefits from remaining active. In addition, preserving a patient’s ability to make a living (again, particularly for patients with chronic conditions such as ESRD) benefits the patient and potentially federal health programs financially. Denying payment for services that were actually delivered, and resulted in sufficient dialysis adequacy value based on the lack of one specific document in the medical record would act as a barrier to patients exercising their rights and to engaging in activities with clear psychosocial benefits.

The standard applied by OIG is incorrect: specific documentation showing medical justification for discontinuation of treatment is not required. We reiterate that there is no binding standard in notice-and-comment rulemaking regarding treatment discontinuation. In addition, even under the non-binding standard cited in the Draft Report, the standard is simply that the discontinuation results from “some unforeseen, but valid reason.” A valid medical reason is merely one form of such “unforeseen, but valid

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<sup>42</sup> 42 C.F.R. § 494.90(a)(6).

reason[s]”. OIG’s articulated standard that “a valid medical reason is documented in the medical record” is therefore even inconsistent with the guidance it cites.

Finally, there is no specific documentation requirement in any guidance for recording the valid reason for early discontinuation, and MACs have not articulated standards for documentation with respect to early discontinuation of treatment. In many, if not all, of the subject claims, a clinician familiar with dialysis treatments—as opposed to a layperson—would understand the valid reason for early termination based on the patient’s medical record.

As described in the claims-specific responses at the end of this Section, a large portion of the claims here have met the appropriate standard. For any remaining claims, a provider ultimately must respect a patient’s autonomy and their decision to terminate treatment early. As discussed, prospective payment was already triggered upon commencement of such patient’s treatment—even in those instances where the patient chooses to end a session early and refuses to offer an explanation.

#### c. Claims-Specific Responses to Finding 2

In addition to the above general comments, which DCI believes are applicable to all claims OIG has identified as having this deficiency, following are DCI’s specific responses to certain individual sample claims, which we have divided into four buckets for ease of explanation.

- i. **Sample 1:** The prescribed treatment duration for this patient was 240 minutes; on May 21, 2018, the patient’s session ended 18 minutes early for a total session time of 222 minutes. However, for the month of May 2018, the patient’s average treatment time was 244 minutes (suggesting that the shortened duration here was compensated for in other sessions), and the patient’s Kt/V for May 2018 was 1.59 (demonstrating the adequacy of the patient’s dialysis).
- ii. **Sample 4:** This patient’s session on October 23, 2018 was prescribed for 240 minutes and ended 10 minutes early for a total session time of 230 minutes. There is ample justification for the early termination in the patient’s medical record; for instance, the patient’s record shows that the patient has dangerous, hypotensive episodes and that the patient was hospitalized with a chest pain incident on October 10, 2018 and again experienced chest pain in the 24 hours prior to the October 23, 2018 session at issue here (as shown on the session’s flowsheet). A clinician familiar with dialysis could reasonably discern from the record that the early termination on October 23, 2018 was due to hypotensive and other cardiac-related complications.
- iii. **Sample 16:** The prescribed treatment duration for this patient was 225 minutes; on November 22, 2018 (Thanksgiving Day), the patient’s session ended 14 minutes early for a total session time of 211 minutes. The patient’s record documents a history of bradycardia and atrial fibrillation, which a clinician familiar with dialysis could reasonably discern from the record as the basis for the early termination. Moreover, for the month of November 2018, the patient’s average treatment time was 228 minutes (suggesting that the shortened duration here was compensated for in other sessions), and the patient’s Kt/V for November 2018 was 1.78 (demonstrating the adequacy of the patient’s dialysis).

- iv. **Sample 17:** The prescribed treatment duration for this patient was 270 minutes; however, this patient had five sessions end early in December 2018 (12/6/18; 12/8/18; 12/11/18; 12/15/18; and 12/24/18)—which nevertheless resulted in a Kt/V for this patient in December 2018 in excess of the Kt/V adequacy threshold. Importantly, this patient had several comorbidities resulting in more frequent complications that could merit early termination. For instance, the patient had serious mobility challenges, including a prosthetic device and motorized wheelchair, and had a history of hypotension and peripheral neuropathy; in particular, patient’s record demonstrates that, beginning in November 2018, midodrine (to treat hypotension) had to be ordered three times daily on days which patient received hemodialysis. Thus, a clinician familiar with dialysis could reasonably discern from the record that the early termination events in December 2018 were due to one or more of the patient’s numerous medical complications:
1. 12/6/18: Flowsheet demonstrates that, during this session, a blood flow rate of 500 could not be achieved and patient experienced bradycardia; during this particular session, the patient’s blood pressure was 119/73 prior to beginning the session and dropped as low as 79/51 prior to the session’s termination.
  2. 12/8/18: Flowsheet demonstrates that patient’s blood pressure measured 176/99 prior to beginning the session and dropped as low as 92/58 prior to the session’s termination.
  3. 12/11/18: Flowsheet demonstrates that patient’s blood pressure was 136/79 prior to beginning the session and dropped as low as 83/61 prior to the session’s termination.
  4. 12/15/18: Flowsheet demonstrates that patient’s blood pressure was 116/66 prior to beginning the session and dropped as low as 94/47 prior to the session’s termination.
  5. 12/24/18 (*Christmas Eve*): Flowsheet demonstrates that patient’s blood pressure was 149/70 prior to beginning the session and dropped as low as 84/57 prior to the session’s termination.
- v. **Sample 23:** The prescribed treatment duration for this patient was 240 minutes; on both December 15, 2018 and December 20, 2018, the patient’s flowsheets demonstrate that the full duration of the prescribed treatment time was met: (1) on December 15<sup>th</sup>, the treatment session commenced at 10:17 A.M. and completed at 14:20 P.M. (2:20 P.M.) for a total of 243 minutes; and (2) on December 20<sup>th</sup>, the treatment commenced at 10:21 A.M. and completed at 14:21 P.M. (2:21 P.M.) for a total of 240 minutes. That said, two other sessions—on December 24, 2018 (*Christmas Eve*) and December 31, 2018 (*New Year’s Eve*)—were terminated 45 minutes and 30 minutes early, respectively. Nevertheless, patient’s Kt/V in December 2018 was 1.40 (demonstrating the adequacy of the patient’s dialysis).
- vi. **Sample 30:** The prescribed treatment duration for this patient was 255 minutes; on October 3, 2018 and October 31, 2018, the patient’s respective sessions ended 43 minutes early (for a total session time of 212 minutes) and 22 minutes early (for a total session time of 233 minutes)—which nevertheless resulted in a Kt/V of 1.36 for October 2018 (demonstrating the adequacy of the patient’s dialysis).
- vii. **Sample 36:** This patient’s session on May 29, 2018 was prescribed for 180 minutes and ended 27 minutes early for a total session time of 153 minutes. The patient’s

medical record contains repeated instances of the patient's non-adherence to the prescribed treatment duration: the patient terminated early with session-specific documentation at least three other times in May 2018 (05/05/18; 05/08/18; and 05/22/18). Nevertheless, the patient's Kt/V for May 2018 was 1.41 (demonstrating the adequacy of the patient's dialysis).

- viii. **Sample 38:** This patient's session on April 6, 2018 was prescribed for 240 minutes and ended 45 minutes early for a total session time of 195 minutes. First, the flowsheet for the April 6<sup>th</sup> session sufficiently documents that the "pt. is only running 3hrs 15 mins today," which begins a pattern in the treatment month of willful early terminations by patient, including on April 13<sup>th</sup> ("pt. has somewhere to be + needs to leave by 2:30") and on April 27<sup>th</sup> ("pt. stated before TX he wanted off at 3pm"). In spite of patient's early termination events, the patient's Kt/V for May 2018 was 1.32 (demonstrating the adequacy of the patient's dialysis).

Furthermore, a clinician familiar with dialysis could reasonably discern from the record that the session was terminated early for valid reasons. For instance, the patient's record documents a low blood glucose event on April 9<sup>th</sup>, which necessitated early termination, and two days later, on April 11<sup>th</sup>, patient complained of sharp chest pain and was sent to the ER; in addition, patient had requested "to go to Hospice."

- ix. **Sample 39:** The prescribed treatment duration for this patient was 210 minutes; however, this patient had four sessions end early in March 2018 (3/7/18; 3/9/18; 3/23/18; and 3/26/18)<sup>43</sup>—which nevertheless resulted in a Kt/V of 1.43 for March 2018 (demonstrating the adequacy of the patient's dialysis). In addition to the objective adequacy of the dialysis patient received during the claim period, the patient's record also undercuts OIG's determinations as to the four sessions:

1. A clinician familiar with dialysis could reasonably discern from the record that two of the sessions (3/7/18 and 3/9/18) were terminated early for valid medical reasons, namely due to hypotensive complications (the patient's blood pressure decreased as low as 87/45 on March 7<sup>th</sup> and as low as 90/44 on March 9<sup>th</sup>).
2. For the other two sessions (3/23/18 and 3/26/18), the actual start and stop times have not been properly captured by OIG's review due to data entry or transcription errors—

On March 23, 2018, the session commenced at 3:36 P.M. and ended at 7:00 P.M. for a total session time of 204 minutes (six minutes shy of OIG's 10-minute threshold); the flowsheet misstates the stop time as 6:30 P.M., but a review of the flowsheet as a whole shows that, although the fluid removed as of 6:30 P.M. measured 1031 cc, 1150 cc total were removed during the session. In other words, dialysis must have persisted past the

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<sup>43</sup> We note also that the medical record evinces certain patterns in non-adherence to the prescribed treatment length which may be indicative of patient preferences. For instance, the patient terminated early with specific termination documentation on Monday, March 5, 2018, which was followed by early terminations in the immediately succeeding sessions on Wednesday (March 7<sup>th</sup>) and Friday (March 9<sup>th</sup>).

misstated stop time because additional fluid was removed after that time. This conclusion is reinforced by the applicable ultrafiltration rate—set at 350/hour or 175/half-hour—which would mean the patient’s session ended around 7 P.M.

On March 26, 2018, the session commenced at 3:40 P.M. and ended around 7:10 P.M. for a total session time at or very near to the prescribed 210 minutes (or 3 hours and 30 minutes, as transcribed in the bold box at the bottom of the row on the session’s flowsheet). This conclusion is reinforced by the total fluid removed, which at the applicable ultrafiltration rate would require the entire treatment length for removal.

- x. **Sample 40:** As documented on the flowsheet for the patient’s session on September 3, 2018, the prescribed 240-minute runtime was reduced to 180 minutes and initialed on the patient’s flowsheet. That said, even if OIG’s finding was correct, the purported recoupment amount for this claim should be tied to the actual reimbursement amount (\$207.45), not the Medicare allowable amount (\$265).
- xi. **Sample 48:** The prescribed treatment duration for this patient was 240 minutes; OIG found that four treatment sessions were terminated early improperly (5/5/18; 5/8/18; 5/22/18; and 5/26/18)—which nevertheless resulted in a Kt/V of 1.55 for May 2018 (demonstrating the adequacy of the patient’s dialysis). In addition to the objective adequacy of the dialysis patient received during the claim period, the patient’s record also undercuts OIG’s determinations as to the four sessions:
  - 1. For May 5, 2018, the patient’s flowsheet demonstrates that the full duration of the prescribed treatment time was met: the treatment session commenced at 10:20 A.M. and completed at 14:24 P.M. (2:24 P.M.) for a total of 244 minutes.
  - 2. For May 8, 2018, the patient’s flowsheet demonstrates that, after pausing for a restroom break around the 200-minute mark, patient requested to end the session, a valid reason for early termination.
  - 3. Additionally, a clinician familiar with dialysis could reasonably discern from the record that one or more of the sessions were terminated early for valid reasons. For instance, the flowsheet for May 8, 2018 shows that, prior to treatment, patient’s blood pressure measured 182/94, but decreased as low as 84/59 prior to termination of the session. Later, on May 15, 2018, the patient was admitted to the ER with severe abdominal pain. In addition, as shown in the treatment record, this patient faced many other challenges that can be barriers to adherence, including: (1) being blind in both eyes, and (2) navigating mobility impairments (patient was both wheelchair dependent and reliant on transportation from SNF to treatment, which the record shows had been unreliable).
- xii. **Sample 49:** The prescribed treatment duration for this patient was 225 minutes; the patient had three sessions end early in May 2018 (5/12/18; 5/24/18; and 5/31/18)—which nevertheless resulted in a Kt/V of 1.36 for May 2018 (demonstrating the adequacy of the patient’s dialysis) and an average treatment

time of 222 minutes for the month (suggesting that the shortened duration was compensated for in other sessions). Moreover, a clinician familiar with dialysis could reasonably discern from the record that one or more of the sessions were terminated early for valid reasons. For instance, the flowsheet for May 24, 2018 shows that the session was terminated early, after the patient reported cramping.

- xiii. **Sample 53:** The prescribed treatment duration for this patient was 180 minutes; the patient had three sessions end early in April 2018 (4/5/18; 4/19/18; and 4/21/18)—which nevertheless resulted in a Kt/V of 1.79 for April 2018 (demonstrating the adequacy of the patient’s dialysis). First, it should be noted that the patient’s record demonstrates that the patient had difficulties relating to both housing and transportation, while records for the treatment month, including on April 23<sup>rd</sup> and April 24<sup>th</sup>, indicate that patient had a pattern of early termination and missed appointments. In fact, the patient was placed on an unstable care plan in April 2018 due to frequently missed treatments, and the patient’s progress note from February 26, 2018 states as follows, “Records 5 missed treatments and 6 early terminations. Educated on dangers of non adherence dialysis regimen. Patient acknowledged understanding dangers.”

Moreover, a clinician familiar with dialysis could reasonably discern from the record that one or more of the sessions were terminated early for valid reasons. For instance, patient was admitted to inpatient hospital care on April 2, 2018 and was discharged on April 4, 2018, one day prior to the first session cited by OIG. The practitioner’s note from April 10, 2018 states that the patient was admitted to the ER in the previous couple of weeks with an infiltrated IV and that the patient has “since [d]eveloped some cellulitis/phlebitis” and that patient was prescribed a 14-day course of Keflex as a result.

- xiv. **Sample 58:** The prescribed treatment duration for this patient was 210 minutes; for all four sessions cited by OIG (6/18/18; 6/20/18; 6/25/18; and 6/27/18), the actual start and stop times have not been properly captured by OIG’s review, possibly due to data entry or transcription errors.

1. On June 18, 2018, the treatment session commenced at 5:25 A.M. and ended at 8:55 A.M. for a total session time of 210 minutes (or 3 hours and 30 minutes, as transcribed in the bold box at the bottom of the row on the session’s flowsheet). The treatment summary documents on/off times as 5:25 A.M. and 8:55 A.M., and although the fluid removed as of 8:30 A.M. measured 2,896 cc, the total amount shown removed as of 8:55 A.M. was 3,300 cc. In other words, dialysis must have persisted past 8:30 A.M. because the flowsheet demonstrates that additional fluid was removed after that time.
2. On June 20, 2018, the treatment session commenced at 5:30 A.M. and ended at 9:00 A.M. for a total session time of 210 minutes (or 3 hours and 30 minutes, as transcribed in the bold box at the bottom of the row on the session’s flowsheet). The treatment summary documents on/off times as 5:30 A.M. and 9:00 A.M., and although the fluid removed as of 8:30 A.M. measured 918 cc, the total amount shown removed as of 9:00 A.M. was 1,000 cc (the ultrafiltration rate was low due to minimal weight gain



following last treatment). In other words, dialysis must have persisted past 8:30 A.M. because the flowsheet demonstrates that additional fluid was removed after that time.

3. On June 25, 2018, the treatment session commenced at 5:30 A.M. and ended at 9:00 A.M. for a total session time of 210 minutes (or 3 hours and 30 minutes, as transcribed in the bold box at the bottom of the row on the session's flowsheet). The treatment summary documents on/off times as 5:30 A.M. and 9:00 A.M., and although the fluid removed as of 8:30 A.M. measured 2,005 cc, the total amount shown removed as of 8:55 A.M. was 2,200 cc. In other words, dialysis must have persisted past 8:30 A.M. because the flowsheet demonstrates that additional fluid was removed after that time.
4. On June 27, 2018, the treatment session commenced at 5:25 A.M. and ended at 8:55 A.M. for a total session time of 210 minutes (or 3 hours and 30 minutes, as transcribed in the bold box at the bottom of the row on the session's flowsheet). The treatment summary documents on/off times as 5:25 A.M. and 8:55 A.M., and although the fluid removed as of 8:30 A.M. measured 1,563 cc, the total amount shown removed as of 8:55 A.M. was 1,700 cc. In other words, dialysis must have persisted past 8:30 A.M. because the flowsheet demonstrates that additional fluid was removed after that time.

Finally, it is worth noting that the patient's Kt/V for June 2018 was 2.0 (demonstrating the adequacy of the patient's dialysis).

- xv. **Sample 60:** The prescribed treatment duration for this patient was 195 minutes; the patient had three sessions end early in December 2018 (12/5/18; 12/14/18; and 12/31/18)—which nevertheless resulted in a Kt/V of 1.57 for December 2018 (demonstrating the adequacy of the patient's dialysis). As an initial matter, the flowsheet for December 5<sup>th</sup> specifically states that the patient's session ended due to air alarms. Moreover, a clinician familiar with dialysis could reasonably discern from the record that one or more of the other sessions were terminated early for valid reasons. For instance, the flowsheets for both December 5<sup>th</sup> and December 31<sup>st</sup> indicate that patient experienced cramping—requiring that the ultrafiltration be decreased or turned off—and the ultrafiltration was similarly turned off on December 14<sup>th</sup> following the patient's complaint of restless legs earlier that week (on December 10<sup>th</sup>).
- xvi. **Sample 61:** The prescribed treatment duration for this patient was 240 minutes for three of the four treatment sessions cited by OIG for early termination deficiencies (5/2/18; 5/3/18; and 5/31/18). As the flowsheet notes, the fourth session on May 16, 2018 was a one-time, *additional* treatment prescribed for 180 minutes ("Extra tx for 3 hours"), which ran for its full duration. For the remaining three sessions, there is sufficient documentation in the record for a clinician familiar with dialysis to reasonably discern that one or more of the sessions were terminated early for valid reasons:

1. Patient's session on May 1, 2018 had to be terminated early (approximately midway) due to patient's admission to the ER; consequently, the May 2, 2018 session was scheduled as a makeup session and also ran for about 120 minutes, for a combined total of 240 minutes. As mentioned, a similar makeup treatment was ordered for May 16, 2018 following patient's valid request to terminate the May 15, 2018 session early. Subsequently, the patient's physician ordered yet another supplemental session on May 29, 2018 in response to patient's continued pattern of high interdialytic weight gain, as well as patient's complaints of ammonia taste and swollen face. Following this pattern of non-adherence and missed treatments, the flowsheet for May 31, 2018 notes that the clinical team reiterated the importance of attending all scheduled treatments and running them for the full treatment time.
2. The flowsheet for May 3, 2018 indicates that the patient experienced cramping—requiring that the ultrafiltration be decreased—and the patient's encounter note from May 1, 2018 also notes that the patient has chronic back pain.

Finally, it is worth noting that the patient's Kt/V for May 2018 was 1.25 (demonstrating the adequacy of the patient's dialysis).

- xvii. **Sample 62:** This patient's session on December 28, 2018 was prescribed for 210 minutes and ended 30 minutes early for a total session time of 180 minutes—which nevertheless resulted in a Kt/V of 1.43 for December 2018 (demonstrating the adequacy of the patient's dialysis). Furthermore, a clinician familiar with dialysis could reasonably discern from the record that the session was terminated early for valid reasons. For instance, the patient's record documents that the patient is wheelchair dependent and that patient was hospitalized on December 10, 2018 with a *C. difficile* infection, and the December 18, 2018 note states that the patient “has unresolved non-chronic infections older than 30 days.”
- xviii. **Sample 66:** The prescribed treatment duration for this patient was 240 minutes; OIG found that three treatment sessions were terminated early improperly (10/12/18; 10/19/18; and 10/24/18)—which nevertheless resulted in a Kt/V of 1.2 for October 2018 (demonstrating the adequacy of the patient's dialysis). There is also sufficient documentation in the record for a clinician familiar with dialysis to reasonably discern that one or more of the sessions were terminated early for valid reasons. For instance, on October 12, 2018, the patient's blood pressure reached as low as 92/38 prior to the session's termination, and the flowsheet notes that the patient experienced clotting around 9:30 A.M., with the session ending shortly thereafter (twelve minutes earlier than prescribed).

The progress note dated October 17, 2018 states that the patient had “purulent drainage at catheter insertion site” and that the associated area of the patient's leg was painful to the touch and reddened; in addition, the patient experienced shortness of breath and the patient was unable to achieve oxygen saturation. According to the progress note, the patient rejected the care team's urging to go to the ER and left the clinic against medical advice. On October 18, 2018, the patient received a graft insertion at the hospital; the following day, October 19, 2018, the

patient's treatment was terminated 16 minutes early.

The next week, the patient terminated the October 24, 2018 session 28 minutes early. During the session on October 24, 2018, the flowsheet shows that the patient required extra fluids on four separate occasions, and the patient was administered antibiotics following the treatment. Per the progress note dated the same day, the patient's "catheter [was] not running well all treatment," and the patient rejected a proposed appointment for catheter revision. Patient was told that if "[they] didn't dialyze well on Friday . . . [they] could end up very sick and in the hospital."

Finally, it is worth noting that the patient scored a 15 on the PHQ-2 on October 26, 2018, indicating a high probability of a depressive episode, which can of course have broad psychosocial effects, including on patient adherence.

- xix. **Sample 71:** The prescribed treatment duration for this patient was 210 minutes; on December 28, 2018, the treatment commenced at 6:35 A.M. and concluded at 10:26 A.M., nine minutes early for a total session time of 231 minutes—which is just shy of OIG's 10-minute threshold. Thus, OIG's finding with respect to the December 28, 2018 session is erroneous. That said, two other sessions (12/26/18 and 12/28/18) included in this Sample did have early terminations greater than or equal to ten minutes—which nevertheless resulted in a Kt/V of 1.24 for December 2018 (demonstrating the adequacy of the patient's dialysis). While there is no specific notation describing the reason(s) for early termination on the individual flowsheets for two remaining sessions, the patient's non-adherence is repeatedly highlighted in the patient's record, including numerous late or missed appointments. For example, the patient missed 4 of the 13 sessions scheduled in December, and the care team educated the patient on the need to be on time in order to receive the full treatment. Accordingly, a clinician familiar with the psychosocial components of dialysis treatment could reasonably conclude that such willful non-adherence by the patient was the cause of the patient's early termination events in December.
- xx. **Sample 75:** The prescribed treatment duration for this patient was 240 minutes; on August 9, 2018 and August 14, 2018, the patient's respective sessions ended 16 minutes early (for a total session time of 194 minutes) and 29 minutes early (for a total session time of 181 minutes—which nevertheless resulted in a Kt/V of 1.78 for August 2018 (demonstrating the adequacy of the patient's dialysis).

As shown in the patient care plan supplied in the Supplemental Information Packet, this patient has had persistent struggles with both being on time for treatment appointments and staying for the full duration of treatments (e.g., "Patient coming late for tx. Patient educated about importance of running full tx;" "Patient educated on staying on the entire treatment. verbalized understanding of same"). While there is no specific notation describing the reason(s) for early termination on the individual flowsheets for OIG's cited sessions, patient's non-adherence is repeatedly highlighted in the patient's record, including in the patient care plan, and a "care plan problem" has been specifically created to address patient's timeliness and non-adherence to prescribed treatment lengths. Accordingly, a clinician familiar with the psychosocial components of dialysis treatment could

reasonably conclude that such willful non-adherence by the patient was the cause of the patient's early termination events in August.

- xxi. **Sample 78:** Exceedingly rare circumstances and clinical considerations animate our discussion of Sample 78: the treatment of a pregnant dialysis beneficiary in November 2018.<sup>44</sup> Pregnancy makes achieving dialysis adequacy much more difficult, even when the patient completes treatments for the prescribed length. In fact, for pregnant patients, the primary clinical goal of treatment is not to achieve dialysis adequacy, but to cause the least hemodynamic instability possible due to the severe risks that hypotension presents to a fetus. As a result, the clinical approach involves more frequent (daily) hemodialysis sessions coupled with gentler, lower filtration rates—"low and slow"—to enable consistent Kt/V values.

As noted earlier, this is the sole sample under Finding 2 with a Kt/V value below Medicare's adequacy threshold because achieving Kt/V stability, as opposed to meeting the adequacy threshold, is the clinical objective for pregnant dialysis patients. Achieving a stable value is paramount to protecting the mother and child, and treatment time must be adjusted from day-to-day accordingly. For instance, among the sessions OIG cited in Sample 78 as having improperly documented early terminations, treatments were terminated anywhere between 48 and 110 minutes early. Prescribing a longer treatment length (here, 180 minutes) that could capture most of the low-and-slow sessions is the most efficient ordering approach; the approach enables clinical staff treating a patient to snip session lengths as necessary, which avoids any last-second efforts to obtain supplemental orders for extended sessions. In other words, early terminations are not a symptom of treating pregnant patients, they are the course of treatment. Because the clinical considerations, including the necessity of early terminations, for treating a pregnant patient would be self-evident to a clinician familiar with dialysis, such clinician could reasonably discern that all of the sessions were terminated early for valid reasons.

- xxii. **Sample 84:** Despite three early termination events during July 2018, patient's Kt/V for the period was 1.63. OIG specifically found the claims submitted for July 2<sup>nd</sup>, July 6<sup>th</sup>, and July 30<sup>th</sup> to be deficient, the treatment durations for which, respectively, were 38, 31, and 20 minutes shorter than the prescribed duration of 240 minutes. This patient's record documents several instances of severe pain in July 2018—including on the allegedly deficient flowsheets for July 2<sup>nd</sup> and July 6<sup>th</sup>—which a clinician familiar with dialysis could reasonably conclude to have been the basis for the patient's early termination events. Finally, we note that, as mentioned in the encounter note dated July 18, 2018, the medical record displays repeated instances of this patient's non-adherence to the prescribed treatment duration. For instance, the patient terminated early with session-specific documentation on July 9, 2018, but the patient refused to sign early termination documentation in at least one instance during that same month (July 27, 2018).
- xxiii. **Sample 91:** This patient's session on April 4, 2018 was prescribed for 210 minutes and ended 30 minutes early for a total session time of 180 minutes. The physician

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<sup>44</sup> In addition to disagreeing with the cited deficiency and standard OIG has applied to this claim, we also note that extrapolation of this unique clinical outlier to the larger claims universe is deeply problematic. *Cf. supra* Section II.

note entered on April 5, 2018 indicates that the April 4<sup>th</sup> session's treatment time was reduced by 30 minutes due to a power outage, which is certainly a "valid reason" for the shortened duration.

- xxiv. **Sample 97:** Despite three treatment sessions with durations shorter than the prescribed 240 minutes during September 2018, patient's Kt/V for the period was 1.84. This patient's record demonstrates that the patient has had a history of cramping associated with dialysis treatments, which a clinician familiar with dialysis could reasonably discern as the basis for early termination events. In addition, this patient's record shows patterns with respect to timing (e.g., in separate sessions, patient reported complications or asked for a 'pause' in the session at or around the session's midpoint (cramping at 7:42 A.M. on September 14<sup>th</sup>; session paused from 7:21 A.M. until 7:45 A.M. on September 10<sup>th</sup>). The patient also terminated early with session-specific documentation on September 28, 2018.
- xxv. **Sample 98:** This patient's session on May 14, 2018 was prescribed for 210 minutes and ended 15 minutes early for a total session time of 195 minutes. There is sufficient medical justification for the early termination in the patient's medical record. The patient's flowsheet shows that, during the session, the patient had a dangerous, hypotensive episode in which the patient's blood pressure decreased as low as 66/31, which also resulted in patient's 'decreased level of consciousness' (as shown on the session's flowsheet). Consequently, a clinician familiar with dialysis could reasonably discern that the early termination was due to the dangerous hypotensive episode experienced during the session.
- xxvi. **Sample 100:** The prescribed treatment duration for this patient was 225 minutes; on April 11, 2018 and April 27, 2018, the patient's respective sessions ended 23 minutes early (for a total session time of 202 minutes) and 11 minutes early (for a total session time of 214 minutes). This patient's non-adherence with respect to treatment duration is specifically noted in the patient's medical record, and the patient terminated early with session-specific documentation on April 6, 2018 and April 23, 2018. Nevertheless, the patient's Kt/V for April 2018 was 1.33 (demonstrating the adequacy of the patient's dialysis).

#### V. **Response to Draft Report Finding 3: "Dialysis Services Not Documented"**

OIG's third finding states that, for 17 claims, "DCI billed for dialysis services for which it did not provide documentation to support some services" ("**Finding 3**").<sup>45</sup> The basis cited by OIG for Finding 3 relates to the "sufficiency of the documentation" contained in the medical record for each beneficiary month, and the majority of claims within Finding 3 (11 of 17) relate to the absence of the patient-generated documentation, sometimes called "flowsheets," for at-home services.<sup>46</sup> In particular, the OIG asserts that

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<sup>45</sup> Draft Report at 10 (internal citations omitted).

<sup>46</sup> For the remaining six claims falling under Finding 3, the cited deficiency indicates a lack of documentation to support the medications billed. As noted to OIG in the Supplemental Information Packet, DCI has implemented numerous controls and procedures to properly track, document, and address medication administration and billing, including an integrated electronic health record with certain medication-related alerts and error messages, as well as protocol for changes in medication orders. Although there was no cited financial impact for such deficiency, in Section V.a.c below, DCI has provided specific responses where records indicate that medication was sufficiently documented.

the lack of patient-generated documentation is enough to completely deny payment on the claim. As described in this Section, Finding 3 is inconsistent with Congressional preferences expressed in the ESRD provisions of the Medicare statute and policy directives of the past two presidential administrations. More importantly, Finding 3 will have a chilling effect on the expansion of home dialysis modalities, which all stakeholders—patients, payor, policymakers, and clinicians—agree are clinically beneficial to patients and the Medicare program. From both a legal and a policy perspective, Finding 3 should have no payment consequences to DCI.

#### a. Home Dialysis Patient-Generated Documentation

Finding 3 would establish a new, rigid standard—unsupported by binding legal authority—that would permit denial of payments solely on the basis of deficiencies in patient-generated documentation. As noted above, the actual standard for assessing the sufficiency of documentation is whether the documentation is sufficient to provide necessary information to make a payment determination.<sup>47</sup> Going beyond this actual binding standard, as Finding 3 does, creates an impermissible “substantive legal standard.” In the normal course of claims processing, CMS (and the MACs acting on its behalf) has taken a less rigid approach toward adjudicating claims reliant on patient-generated documentation, and does not deny payment based on deficiencies in patient-generated documentation. This is evidence that the ultimate question of whether MACs have been provided the “information was necessary to make a payment determination” has been satisfactorily answered.

We note also that patient-generated documentation is primarily relevant to assessing “quality of care” under the CFCs, which are enforced through routine surveys by state certification agencies.<sup>48</sup> This type of documentation does not affect payment.<sup>49</sup> For example, the Medicare Claims Processing Manual,

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<sup>47</sup> 42 C.F.R. § 424.5(a)(6).

<sup>48</sup> See, e.g., *Hawaii ex. rel. Torricer v. Liberty Dialysis-Hawaii LLC*, 512 F.Supp.3d 1096, 1115-1116 (D. Haw. 2021) (“Ultimately, whether labeled as conditions of payment or of participation, a violation of Part 494’s ‘conditions for coverage’ for ESRD facilities does not mean that any particular claim for payment will not be reimbursed. A violation does not automatically exclude payment, much less necessarily exclude qualification for payment . . . [I]n order to participate in the Medicare program, defendant, a dialysis center providing treatment for ESRD, must meet and adhere to these ‘conditions’ as standards for the quality of care.”) (internal citations omitted).

<sup>49</sup> See, e.g., *Liberty Dialysis-Hawaii*, 512 F.Supp.3d at 1115 (D. Haw. 2021) (“§ 413.210(a) and Part 494 establish requirements so that a facility *can* be paid—by definition, they are base level conditions for an ESRD facility to *qualify* to provide services (i.e., conditions for ‘coverage’). For purposes of Medicare, 42 C.F.R. § 488.1 specifically defines ‘conditions for coverage’ as ‘mean[ing] the requirements suppliers must meet to *participate* in the Medicare program.”) (emphasis in original); *U.S. v. Dialysis Clinic, Inc.*, Medicare & Medicaid Guide (CCH) ¶ 303,647 (N.D.N.Y. Jan. 19, 2011) (“The language in 42 C.F.R. § 494 clearly establishes a condition of participation, not prerequisites to receiving reimbursement from the government. While the scope of § 494 is clearly defined in § 494.1, the text of the remaining sections, 494.20 through 494.180, further support the conclusion that the regulations provide conditions of participation, not payment. Sections 494.20 through 494.180 apply to ‘conditions’ relating to, *inter alia*: infection control, water and dialysate quality, reuse of hemodialyzers, care at home, quality assessment, physical environment, patients rights, patient assessment, personnel qualifications and medical records. In order to participate in the Medicare program, defendant, a dialysis center providing treatment for ESRD, must meet and adhere to these ‘conditions’ as standards for the quality of care.”) (citing *U.S. ex rel. Landers v. Baptist Memorial Health Care Corp.*, 525 F.Supp.2d 972, 978 (W.D. Tenn. 2007) for the proposition that “‘conditions of participation’ are quality of care standards directed towards an entity’s continued ability to participate in the Medicare program, not a prerequisite for a particular payment”). See also *U.S. v. DaVita Inc.*, No. 8:18-cv-01250-JLS-DFM, 2020 WL 3064771, at \*5 n.6 (C.D. Cal. Apr. 10, 2020) (surveying the caselaw and concluding that the provisions of “42 C.F.R. § 494 *et seq.* have . . . been found by courts to constitute ‘conditions of participation [in the

offering guidance on payments for dialysis treatments, states: “The equivalent weekly or daily [intermittent peritoneal dialysis (IPD)] or [continual ambulatory peritoneal dialysis (CAPD)]/[continuous cycling peritoneal dialysis (CCPD)] payment does not depend upon the number of exchanges of dialysate fluid per day (typically 3-5) or the actual number of days per week that the patient undergoes dialysis. The weekly (or daily) rate is based on the equivalency of one week of IPD or CAPD/CCPD to one week of hemodialysis, regardless of the actual number of dialysis days or exchanges in that week.”<sup>50</sup>

In effect, the standard OIG would create through Major Finding 3 would deny payment to DCI, not because of any flaw in DCI’s compliance program, but because of beneficiary non-adherence.

#### **b. Medicare Home Dialysis Policy**

Since the inception of the Medicare ESRD benefit, the Medicare statute has expressed a preference that patients receive treatment in their homes, to the extent possible, rather than in ESRD facilities. The statute provides that “[i]t is the intent of Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated.”<sup>51</sup> CMS has undertaken many initiatives over the years to promote and increase the prevalence of home dialysis modalities in recognition of both the clear clinical benefits to patients, as well as fiscal benefits to the Medicare program. This long-standing goal of increasing home dialysis was most recently reiterated in an executive order issued under the Trump administration, which has continued in effect under the Biden administration, that directed HHS to implement multiple significant programs to incentivize home dialysis over in-center dialysis treatments.<sup>52</sup>

For 11 of the 17 claims identified in Finding 3, the basis for OIG’s conclusion that the claims had been overpaid was “DCI did not provide dialysis treatment notes during 162 home dialysis sessions associated with 11 claims . . .” In addition to CfCs under Part 494,<sup>53</sup> the Draft Report cites the same statutory and regulatory authority for general documentation requirements as it does under Finding 2 (Social Security Act § 1833(e); 42 C.F.R. §§ 424.5(a)(6) and 494.170). As we noted above, when the medical records discussed in Finding 3 are viewed in their entirety, the claims include documentation “sufficient [] to determine whether payment is due and the amount of payment.”<sup>54</sup> In addition, as HHS stated in the *Time Transmittal rescission*: seeking to impose a binding new requirement “through sub-regulatory issuances, to require *the submission of additional data or other information not listed in the regulation*, it is invalid, as this would be an unlawful end-run around the notice-and-comment requirements of the APA and Social Security Act Section 1871.”

The lack of perfect documentation does not disqualify payment for an ESRD treatment, provided that it is sufficient, and in these cases, the documentation issues raised in the Draft Report are immaterial

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Medicare program generally], rather than prerequisites to receiving reimbursement [for specific treatments]”) (bracketed text in original).

<sup>50</sup> *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 80.4.

<sup>51</sup> 42 U.S.C. § 1395rr(c)(6).

<sup>52</sup> Executive Order on Advancing American Kidney Health (Order 13879), issued July 10, 2019, *available at* <https://www.govinfo.gov/content/pkg/FR-2019-07-15/pdf/2019-15159.pdf>; *see also* CMS, Fact Sheet re: CY 2022 End Stage Renal Disease Prospective Payment System Final Rule (CMS-1749-F) (Oct. 29, 2021) (strengthening the ESRD Treatment Choices program borne of Executive Order 13879 in order “to decrease disparities in rates of home dialysis . . . among ESRD patients with lower socioeconomic status”).

<sup>53</sup> As discussed in Notes 48 and 49, *supra*, federal courts have concluded such CfCs do not affect payment decisions.

<sup>54</sup> 42 C.F.R. § 424.5(a)(6).

to payment decisions. The absence of a specific piece of documentation does not render a claim non-payable, particularly where other forms of documentation are present in the record and substantiate that the services were actually provided and were medically necessary. While we do not believe there is a clear legal or regulatory basis for denying payments under Finding 3, the implications of the OIG's position on this point are quite clear with respect to home dialysis patients.

DCI educates home dialysis patients extensively on what documentation is required of them and engages with patients who exhibit a pattern of poor documentation. But because home dialysis is by definition performed outside of a licensed dialysis facility staffed with medical professionals, it is inevitable that documentation maintained by chronically ill patients (as opposed to medical professionals trained in documentation) will not always be completed to the same standards.<sup>55</sup> DCI takes seriously its responsibility to ensure that home dialysis services are equivalent to those furnished in a dialysis facility, as required under 42 C.F.R. § 494.100. DCI's ability to ensure high quality, in-center equivalent dialysis treatments is unaffected by the types of immaterial documentation imperfections identified in Finding 3.

On the other hand, if the OIG's position is that home dialysis payments for services that were actually performed should be denied based on immaterial documentation flaws, publication of the Draft Report will have a significant chilling effect on the decades-long, bipartisan goal of expanding home ESRD services in the Medicare program. If dialysis facilities are faced with non-payment because patients (who are not under the dialysis facilities' control) supply imperfect documentation, the clear signal OIG would be sending to dialysis facilities would be that it is safer to keep otherwise appropriate home dialysis candidates in dialysis facilities for in-center treatment.

Since the time of the audit and in conformity with OIG's recommendations, DCI has continued to emphasize and re-emphasize—through training, pre-programmed electronic records protocol, and beneficiary outreach—how and why beneficiaries and staff must create, maintain, and deliver proper documentation of dialysis treatments, with special emphasis on at-home treatments and the accompanying patient-generated documentation.

### c. Claims-Specific Responses to Finding 3

In addition to the above general comments, which DCI believes are applicable to all claims OIG has identified as having this deficiency, following are DCI's specific responses to certain individual sample claims.

- i. **Sample 2:** As noted in the Supplemental Information Packet, DCI disagrees with OIG's finding that DCI did not provide documentation to support the medications billed for this patient. Specifically, the Sensipar listed as 1800 Serv. Units on the claim had a documented prescription.
- ii. **Sample 10:** OIG's finding suggests that, for Sample 10, 13 treatment dates lack sufficient documentation. We note that DCI has provided PD clinic visit sheets for January 4, 2018 and January 15, 2018. As a result, if OIG's theory regarding

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<sup>55</sup> The absence of patient-generated documentation does not necessarily mean sufficient patient-generated documentation was not created; since patients must also maintain the documentation for weeks at a time and must ultimately deliver the documentation to the clinic, such documentation is often simply lost along the way or forgotten at home.



- the financial impact of this finding were true, the amount of overpayment (\$1,125.02) would need to be reduced by 2/13<sup>th</sup>, at minimum.
- iii. **Sample 14:** OIG’s finding suggests that, for Sample 14, sufficient documentation was not provided to support the medications billed. We note that the patient skipped treatment on March 7, 2018, and as a result, DCI did not bill for hectorol on that date.
  - iv. **Sample 28:** OIG’s finding suggests that, for Sample 28, 24 treatment dates lack sufficient documentation. We note that one weekly flowsheet, as well as PD clinic visit documentation for March 28, 2018, have been provided. As a result, if OIG’s theory regarding the financial impact of this finding were true, the amount of overpayment (\$1,789) would need to consequently be reduced by 1/24<sup>th</sup>, at minimum.
  - v. **Sample 34:** OIG’s finding suggests that, for Sample 34, sufficient documentation was not provided to support the medications billed. We note that the patient skipped treatment on several dates (02/06/18; 02/08/18; 02/10/18; and 02/15/2018); however, no medications were billed on those dates, and the actual claim dates align with the administration days on the patient’s flowsheets.
  - vi. **Sample 44:** DCI disputes OIG’s finding for Sample 44. Flowsheets for each of the associated treatment dates in Sample 44 have been provided to OIG.
  - vii. **Sample 55:** Sample 55 emanates from the care of a young ESRD patient who was trying to lose weight in order to qualify for a transplant. While DCI understands that the patient-generated documentation for this patient was imperfect, the record tells the story of a patient who was active in his or her care and motivated to meet clinical benchmarks. DCI supports the care team’s decision to continue treating this individual in spite of the patient’s non-adherence to self-reported documentation requirements during the month in question, but DCI welcomes any further recommendations OIG may have for disincentivizing or otherwise avoiding such non-adherence.
  - viii. **Sample 66:** The specific deficiency cited for Sample 66 should not have been included in Finding 4. Influenza vaccinations are administered once per year, as a courtesy to DCI’s patients. Extrapolating Sample 66’s alleged deficiency and its accompanying financial impact to the entire universe of *monthly* claims for ESRD services submitted by DCI is not appropriate, either in terms of scope or subject matter.<sup>56</sup> Even if OIG ultimately finalizes its individual conclusion with respect to Sample 66, in the interest of fairness, any alleged financial impact should not be extrapolated to the larger claims universe.

**VI. Response to Draft Report Finding 4: “Height and Weight Measurements Did Not Comply with Medicare Requirements”**

OIG’s fourth finding states that, “[f]or 12 claims, DCI claimed dialysis services for which weight (11 claims) and height (1 claim) measurements did not comply with Medicare requirements” (“**Finding 4**”). A dialysis patient’s height and weight measurements are clinical parameters that factor into the

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<sup>56</sup> As OIG notes in footnote 21 of the Draft Report, “[a] claim consists of all *dialysis services* furnished to an individual beneficiary by a dialysis facility during a calendar month” (citing *Medicare Claims Processing Manual*, Pub. No. 100-04, ch. 8, § 50.3 and ch. 1 § 50.2.2) (emphasis added).

treatment the dialysis patient receives. A form of daily self-care delivered in the home, patients are ultimately responsible for their own peritoneal dialysis treatment since facility staff have no direct involvement. This responsibility comes with many rewards, however, chiefly that patients are able to continue to work, travel, and carry on their lives in spite of chronic illness. That said, facility staff provide important training and education to at-home PD patients upon admission, and the facility staff continue to educate, monitor and support at-home PD patients throughout their treatment. Such initial and continuing education includes training patients on the critical role in care played by the documentation patients generate themselves. Nevertheless, facilities must ultimately rely upon patients to comply with documentation requirements because, as mentioned, patients' in-home PD sessions are not attended or facilitated by clinical staff.

DCI's clinical requirements with respect to height/weight measurements are consistent with Medicare guidance, and DCI has clinical systems and controls in place to monitor and alert practitioners about required measurements. For example, in some instances, DCI's internal system does not permit practitioners to complete edits to a flowsheet without first clarifying certain measurement discrepancies in the patient's electronic chart.

Although there was only a limited financial impact as a result of Finding 4, DCI takes documenting the appropriate and accurate biometric data of its patients seriously. DCI continues to seek adherence to existing internal controls and to explore additional opportunities to ensure timely recording of patient data, including patient weights. We note, however, that many of the same issues with patient-generated documentation described in DCI's reply to Finding 3 are also present for the claims identified under Finding 4. Ultimately, DCI relies heavily upon patient documentation for home dialysis services, and DCI has clinical systems and controls in place to integrate patients' self-reported measurements into the medical record. Nevertheless, DCI cannot force patients to provide self-reported data, and denying care to patients for their imperfect documentation would seriously harm efforts to increase adoption of home dialysis in line with the stated goals of HHS and CMS. DCI will continue, consistent with OIG's recommendations, to emphasize and re-emphasize—through training, pre-programmed electronic records protocol, and beneficiary outreach—how and why beneficiaries and staff must create, maintain, and deliver proper documentation of patient biometric data.

Finally, we note that OIG may have overestimated the financial impact of this category. First, even accepting OIG's findings as true, the financial impact has been overstated to some degree. According to Appendix E of the Draft Report, OIG identified two claims under Finding 4 that had an alleged overpayment: Sample 19 in the amount of \$196 and Sample 57 in the amount of \$13. Accordingly, the combined sum of Finding 4's alleged overpayment should be \$209, not \$210. Notably, however, the Draft Report does not make clear OIG's basis for such sum, *e.g.*, was it derived from the difference in payment as calculated using the actual weight versus the recorded weight, an undoubtedly marginal amount? Moreover, in at least three of the claims sampled by OIG (Samples 28, 47, and 90), the weight value submitted on DCI's claim likely resulted in marginal underpayments to DCI. While the figures may seem insignificant at first glance, they are nevertheless given significant purchase in the Draft Report due to the vast claims universe and extrapolation methodology employed by OIG.

**VII. Response to Draft Report Finding 5: “Lack of Physician’s Monthly Progress Notes in the Medical Records”**

OIG’s fifth finding states that “[f]or two claims, there was no documentation in the medical record to support that beneficiaries were seen by a physician or other qualified practitioner at least monthly” (“**Finding 5**”).<sup>57</sup>

DCI has clinical systems and internal controls in place to ensure complete progress notes. As stated in the Supplemental Information Packet and acknowledged by OIG in the Draft Report, DCI began implementing an electronic practitioner progress note module into its information systems in October 2019, although the transition to the electronic progress note module has been slowed due to the COVID-19 pandemic. DCI trains its practitioners on the required elements of progress notes, whether recorded by paper or electronically, and for clinics that have transitioned to the electronic module, DCI provides training on how to use the electronic flowsheet and chairside charting system, including on proper practitioner rounding that results in a progress note.

For facilities not yet transitioned to the new progress note module, or where a practitioner desires to use paper forms, a paper encounter note is printed for both in-center and home patients, which pulls real-time information from the patient’s electronic medical record. When a practitioner uses such encounter note for paper documentation, they can complete it by reviewing key information about the patient’s treatment therapy, lab data, and medications (both in-facility and at-home) by all providers involved in the patient’s care, and practitioners can document any changes deemed necessary to improve the patient’s medical condition by entering it on the paper note. As part of the note review process, the practitioner has the ability to interact with the patient and complete a physical exam and document the findings accordingly.

Once completed, encounter notes and electronic progress notes are filed in the patient’s chart, and for paper notes, staff can then document the paper note as an encounter in the electronic record. Multi- and single-patient audit reports can be generated, viewed, or printed by staff and practitioners. Such reports validate not only the patient’s treatment dates for the month, but also the days the patient was seen by a practitioner and whether/when an encounter note was signed.

While Finding 5 has no financial impact, DCI takes seriously the requirement that practitioners see beneficiaries as required under the Medicare regulations, and in both of the samples in question, we have been able to confirm through a larger view of the medical record and interviews with the relevant practitioners and patients that the patients implicated were seen at least monthly. Nevertheless, consistent with OIG’s recommendations, DCI continues to emphasize the importance of fully documenting physician encounters and to encourage its clinics and clinicians to transition toward a more integrated and comprehensive recordkeeping system by adopting the electronic progress note module.

**VIII. Final Considerations & Conclusions**

DCI appreciates the OIG’s engagement throughout the audit process and the opportunities OIG has identified for process improvements. However, DCI strongly objects to the OIG’s audit design, extrapolation methodology, and the legal bases for the OIG’s overpayment determinations, particularly under Findings 2 and 3. As explained above and in the Expert Report, the OIG’s sample design is fundamentally flawed and therefore should not be extrapolated to the entire universe of claims covered by

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<sup>57</sup> Draft Report at 14.

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the Draft Report. In addition to the statistical deficiencies in the Draft Report, the overpayment determinations under Findings 2 and 3 are unsupported by binding legal authority. In fact, just last year, HHS issued statements that directly contradict the Draft Report's cited authority for determining overpayments under Findings 2 and 3.

Removal of either Finding 2 or Finding 3 would significantly decrease the error rate in the audit such that any reasonable threshold for extrapolation would no longer be met. To the extent there were, in fact, deficiencies in DCI's claims under Findings 2 or 3, the appropriate remedies supported by binding legal authority are not financial.

Taken together, the statistical shortcomings and erroneous application of Medicare regulations set forth in the Draft Report would result in liability to DCI completely out of proportion to the alleged underlying documentation issues identified by the OIG. These results are not only unjustified as applied to DCI; they run contrary to long-standing Medicare policy priorities aimed at improving patient choice, quality of care, and quality of life.

Thank you for your attention to this matter. We appreciate the opportunity to work with OIG throughout this process, and we would welcome the opportunity to answer any questions you may have. Please do not hesitate to contact me.

Very truly yours,

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