

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**MEDICARE DIALYSIS  
SERVICES PROVIDER  
COMPLIANCE AUDIT:  
BIO-MEDICAL APPLICATIONS  
OF ARECIBO, INC.**

*Inquiries about this report may be addressed to the Office of Public Affairs at  
[Public.Affairs@oig.hhs.gov](mailto:Public.Affairs@oig.hhs.gov).*



**Amy J. Frontz  
Deputy Inspector General  
for Audit Services**

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# *Office of Inspector General*

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## Report in Brief

Date: March 2020

Report No. A-02-17-01016



### 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 Bio-Medical Applications of Arecibo, Inc. (BMA), for audit because it ranked among the highest-paid providers of dialysis services in Puerto Rico and Medicare surveyors identified various health and safety issues.

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

### How OIG Did This Audit

Our audit covered 6,726 beneficiary-months for which BMA received Medicare reimbursement totaling almost \$11.5 million for dialysis services provided during calendar years 2015 and 2016. We reviewed a random sample of 100 beneficiary-months. A beneficiary-month was defined as all dialysis services provided to a beneficiary during 1 calendar month. We evaluated the services for compliance with Medicare requirements and submitted them to independent medical review.

## Medicare Dialysis Services Provider Compliance Audit: Bio-Medical Applications of Arecibo, Inc.

### What OIG Found

BMA claimed reimbursement for dialysis services that did not comply with Medicare requirements during 96 out of 100 sampled beneficiary-months. Specifically, BMA submitted claims for which (1) plans of care and/or comprehensive assessments did not meet Medicare requirements, (2) beneficiaries' height and/or weight measurements did not comply with Medicare requirements, (3) there were no valid physicians' orders, (4) dialysis treatments were not completed, (5) ESRD measurements were not supported and (6) home dialysis services were not documented.

While BMA had internal controls to monitor and maintain complete, accurate, and accessible medical records, these controls were not always effective or followed to ensure that its claims for dialysis services complied with Medicare requirements.

We estimated that BMA received unallowable Medicare payments of at least \$96,185 for dialysis services that did not comply with Medicare requirements. Most of the errors we identified did not affect BMA'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 BMA Comments

We recommend that BMA refund an estimated \$96,185 to the Medicare program. We also made a series of recommendations to strengthen BMA's internal controls to ensure that dialysis services comply with Medicare requirements.

In written comments on our draft report, BMA did not indicate concurrence or nonconcurrence with our recommendations but described actions it has taken and plans to take to address some of them. BMA generally disagreed with our findings and provided additional documentation under separate cover. BMA also stated that our sampling methodology was flawed and that there was no statistically valid use for it. After reviewing BMA's comments and the additional documentation, we revised our determinations for 17 beneficiary-months 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 REVIEW**

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) 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.<sup>1</sup>

We reviewed claims for dialysis services submitted for Medicare reimbursement by Bio-Medical Applications of Arecibo, Inc. (BMA), because it ranked among the highest-paid providers of ESRD services in Puerto Rico and Medicare surveyors identified various health and safety issues.

### **OBJECTIVE**

Our objective was to determine whether dialysis services provided by BMA 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. Novitas Solutions, Inc. (Novitas), is the MAC that processes and pays the Medicare claims submitted by BMA.

OIG believes that this audit report constitutes credible information of potential overpayments. Providers that receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any overpayment

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

amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (60-day rule).<sup>2</sup>

## **Medicare Dialysis Services**

Medicare Part B covers dialysis services, items, supplies, and equipment provided in approved facilities to beneficiaries with ESRD.<sup>3</sup> Medicare pays dialysis facilities on a bundled per-treatment basis through CMS's ESRD Prospective Payment System. 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>4</sup> CMS adjusts the bundled payment to account for patient age, height and weight, and comorbidities.<sup>5, 6</sup>

To qualify for Medicare payments, dialysis facilities must meet the conditions for coverage (CfC) described in 42 CFR part 494.<sup>7, 8</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>9</sup>

Payment for dialysis services will only be made if a physician certifies services are or were medically required.<sup>10</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>11</sup>

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<sup>2</sup> The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

<sup>3</sup> The Act, §§ 1832(a), 1861(s)(2)(f), and 1881(a).

<sup>4</sup> The Act, § 1881(b)(14)(B); 42 CFR §§ 413.171 and 413.217.

<sup>5</sup> 42 CFR § 413.235.

<sup>6</sup> Comorbidities are patient-specific conditions that are secondary to the patient's principal diagnosis that necessitates dialysis, yet have a direct affect on dialysis.

<sup>7</sup> 42 CFR § 413.210(a).

<sup>8</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>9</sup> 42 CFR §§ 494.80 and 494.90.

<sup>10</sup> The Act, §§ 1835(a)(2)(B), 1861(s)(2)(F), and 1881(b)(14)(B).

<sup>11</sup> The Act, § 1833(e); 42 CFR §§ 424.5(a)(6) and 494.170.



## **Bio-Medical Applications of Arecibo, Inc.**

BMA, headquartered in Waltham, Massachusetts, is owned by Fresenius Medical Care Holdings, a dialysis provider offering services and products throughout the United States, including Puerto Rico. During calendar years (CYs) 2015 through 2016 (audit period), BMA operated 4 dialysis centers in Puerto Rico, providing two types of treatments: in-center hemodialysis and home therapy.<sup>12</sup>

## **HOW WE CONDUCTED THIS REVIEW**

Our review covered 6,726 beneficiary-months<sup>13</sup> for which BMA received Medicare reimbursement totaling \$11,461,195 for dialysis services provided during the audit period. We reviewed a random sample of 100 beneficiary-months. We obtained medical records for each sample item to determine whether services complied with Medicare requirements. We also submitted these medical records to an independent medical review contractor who determined whether services were medically reasonable and necessary and met Medicare requirements.

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**

BMA claimed dialysis services that did not comply with Medicare requirements during 96 of the 100 sampled beneficiary-months. Specifically,

- During 67 beneficiary-months, plans of care and/or comprehensive assessments did not meet Medicare requirements.
- During 68 beneficiary-months, the associated beneficiary's height and/or weight were not measured in accordance with Medicare requirements.
- During 21 beneficiary-months, physicians' orders for dialysis services were not valid.

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<sup>12</sup> In-center hemodialysis services are those furnished in a Medicare-certified ESRD facility on an outpatient basis. Home therapy modalities include both continuous ambulatory peritoneal dialysis and continuous cycler peritoneal dialysis.

<sup>13</sup> A beneficiary-month was defined as all dialysis services provided to a Medicare beneficiary by BMA during 1 calendar month.

- During nine beneficiary-months, dialysis treatments were not completed.
- During seven beneficiary-months, BMA reported ESRD measurements that were not supported.
- During seven beneficiary-months, there was no documentation to support some of the home dialysis services BMA billed to Medicare.

The total exceeds 96 because 61 of the beneficiary-months contained more than 1 error.

While BMA had internal controls to monitor and maintain complete, accurate, and accessible medical records, these controls were not always effective or followed to ensure that its claims for dialysis services complied with Medicare requirements.

Most of the errors we identified did not affect the Medicare reimbursement BMA received because Medicare pays for dialysis on a bundled per-treatment basis or because the findings relate to Medicare CfCs. These findings, however, could have a significant effect on the quality of care BMA provided to Medicare beneficiaries and may have resulted in inappropriate or unnecessary treatments.

On the basis of our sample results, we estimated, for errors that affected reimbursement, BMA received unallowable Medicare payments of at least \$96,185 during the audit period.<sup>14</sup> As of the publication of this report, this unallowable amount includes claims outside the 4-year Medicare claims reopening period.<sup>15</sup>

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

An interdisciplinary team is responsible for providing dialysis patients with individualized, comprehensive assessments of their needs.<sup>16</sup> The comprehensive assessment must be used to develop the patient's plan of care.<sup>17</sup> The interdisciplinary team must also develop and implement a written, individualized comprehensive plan of care that specifies the services

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<sup>14</sup> To be conservative, we recommend recovery of overpayments at the lower limit of a 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.

<sup>15</sup> 42 CFR § 405.980(b)(2) (reopening for good cause).

<sup>16</sup> The comprehensive 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>17</sup> 42 CFR § 494.80.

necessary to address the beneficiary's needs identified in the comprehensive assessment. The plan of care must be signed by all members of the interdisciplinary team and Medicare beneficiary.<sup>18</sup>

Implementation of the initial plan of care must begin within the latter of 30 calendar days after admission to the dialysis facility or 13 outpatient hemodialysis sessions beginning with the first outpatient dialysis session. A follow-up comprehensive 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>19</sup> Additionally, revisions to the plan of care and comprehensive assessments are required to be conducted at least annually for stable patients and at least monthly for unstable patients.<sup>20</sup>

During 67 beneficiary-months, BMA claimed Medicare reimbursement for dialysis services for which the plan of care (62 beneficiary-months) or comprehensive assessment (27 beneficiary-months) did not comply with certain Medicare requirements.<sup>21</sup> Instances of noncompliance included plans of care that (1) did not contain all required elements (47 beneficiary-months), (2) were not documented (10 beneficiary-months), (3) were not timely updated (5 beneficiary-months), (4) were not signed by all members of the interdisciplinary team (2 beneficiary-months), and (5) were for the wrong type of dialysis service or for the wrong type of dialysis access port (2 beneficiary-months).<sup>22</sup> In addition, comprehensive assessments (1) did not contain all required elements (18 beneficiary-months), (2) were not timely updated (10 beneficiary-months), (3) were not documented (2 beneficiary-months), and (4) were unrelated to the type of dialysis services the beneficiary was receiving (2 beneficiary-months).<sup>23</sup>

While BMA had internal controls to monitor and maintain complete, accurate, and accessible medical records, these controls were not always effective in ensuring compliance with the Medicare requirements. Specifically, BMA's health record system sends an initial electronic alert to BMA staff and will continue to send alerts if an assessment is not completed, including details on missing signatures, missing or incomplete required elements, and timeliness. Despite these controls, BMA staff did not comply with certain Medicare requirements for plans of care and comprehensive assessments during 67 beneficiary-months.

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<sup>18</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).

<sup>19</sup> 42 CFR § 494.80(b)(2).

<sup>20</sup> 42 CFR § 494.80.

<sup>21</sup> Total exceeds 67 because 22 beneficiary-months contained both deficiencies.

<sup>22</sup> Total exceeds 62 because 4 beneficiary-months contained more than 1 of these deficiencies.

<sup>23</sup> Total exceeds 27 because 5 beneficiary-months contained more than 1 of these deficiencies.

BMA's failure to ensure plans of care and comprehensive assessments complied with Medicare requirements did not result in improper Medicare payments; however, it could result in inadequate treatment planning and could preclude beneficiaries from receiving needed services.

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

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. 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 their height must be measured no less frequently than once per year.<sup>24</sup>

During 68 beneficiary-months, BMA submitted claims for dialysis services for which height and/or weight measurements did not comply with Medicare requirements. Specifically, during 64 beneficiary-months, more than 1 year had passed since BMA documented that it measured the associated beneficiary's height.<sup>25</sup> In addition, during seven beneficiary-months, a beneficiary had not been weighed immediately following the last home dialysis session of the month.<sup>26, 27</sup>

While BMA had internal controls in place to annually measure patients' heights, these errors occurred because BMA's controls only required documenting annual measurements if patients' heights changed. Specifically, BMA did not update the beneficiaries' health record to reflect the yearly dates of when their heights were measured. Rather, BMA only updated its records to reflect when it recorded changes in beneficiaries' heights. As a result, for a beneficiary whose height did not change from one year to the next, there was no evidence that BMA complied with the annual height measurement requirement. Additionally, BMA's procedures required the weight for a home dialysis beneficiary to be taken during a monthly visit to the facility—not always the last dialysis session of the month.

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<sup>24</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.

<sup>25</sup> Height measurements were documented as taken between 1 day and nearly 13 years after the 1-year requirement.

<sup>26</sup> Home dialysis patients are given a scale so that they can weigh themselves before and after each dialysis treatment. The patient is then responsible for documenting their weight on a flowsheet that is provided to BMA for inclusion in the medical record.

<sup>27</sup> Total exceeds 68 because 3 beneficiary-months contained both deficiencies.

We could not determine whether any of these errors had an impact on the Medicare reimbursement that BMA received because the height and weight measurements needed to determine the correct amount of Medicare reimbursement were not available.<sup>28</sup> However, 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 potentially result in a beneficiary receiving inappropriate dialysis treatments.

## **PHYSICIANS' ORDERS NOT VALID**

According to Medicare requirements, payment for dialysis services furnished to beneficiaries must be supported by a physician's order certifying that such services are or were medically required.<sup>29</sup>

During 21 beneficiary-months, BMA claimed reimbursement for ESRD laboratory services and drugs for which it did not provide a valid physicians' order. Specifically, BMA claimed reimbursement during eight beneficiary-months for which a physician's order had expired when the services were provided<sup>30</sup> and during two beneficiary-months for which the physician's order was not yet effective.<sup>31</sup> BMA also claimed reimbursement during 13 beneficiary-months for laboratory services for which physician's orders were not signed.<sup>32</sup>

While BMA had internal controls to ensure that dialysis services were properly ordered, BMA staff did not ensure that a valid physician's order was in place when the services were provided. BMA also had internal controls to alert physicians when their orders were not signed; however, these controls failed to prevent these errors. Additionally, BMA's internal controls required staff to review a sample of beneficiaries' medical records on a monthly basis to ensure that dialysis services were properly ordered. If staff identified issues with physicians' orders, BMA contacted the associated physicians and instructed them to make necessary corrections. However, physicians did not always make these corrections and BMA did not follow up with them.

BMA also indicated that, during our audit period, its dialysis facilities were transitioning from paper to electronic records. Therefore, some physicians' orders may have been entered into a beneficiary's clinical record as "Transcribed." In these instances, the physicians would have provided orders on paper and nurses would have transcribed them into BMA's electronic

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<sup>28</sup> CMS adjusts the bundled payment to account for various patient-specific factors, including height and weight.

<sup>29</sup> The Act, §§ 1835(a)(2)(B), 1861(s)(2)(F), and 1881(b)(14)(B), and 42 CFR §§ 410.12(a)(3), 410.32, and 424.10.

<sup>30</sup> A physician's order had expired between 1 and 9 days before the services were provided.

<sup>31</sup> Services were provided between 1 and 18 days prior to the effective date of the physician's order.

<sup>32</sup> Total exceeds 21 because 2 beneficiary-months contained both deficiencies.

recordkeeping system. For some cases, BMA stated that it was not able to locate the paper records associated with these transcribed orders.<sup>33</sup>

Because ESRD laboratory services and drugs are paid on a bundled per-treatment basis, the monetary impact for these services in error cannot be calculated. However, physicians may not have been adequately involved in the care provided to their patients, which may have resulted in the provision of medically unnecessary services and prescription errors.

## **DIALYSIS TREATMENTS NOT COMPLETED**

If a dialysis treatment is started but not completed for some unforeseen reason, and a valid medical 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>34</sup>

During nine beneficiary-months, BMA claimed Medicare reimbursement for a dialysis treatment that was 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 medical reason for discontinuing treatment or the beneficiary's refusal of treatment.<sup>35</sup>

While BMA had internal controls for documenting the medical reason for discontinuing treatment or a beneficiary's refusal of treatment, BMA staff did not always document these reasons. Failure to complete dialysis treatments could result in a beneficiary not receiving needed treatments and could be detrimental to the beneficiary's health. Dialysis treatments not completed as prescribed could lead to fluid overloads and metabolic problems.

## **END-STAGE RENAL DISEASE MEASUREMENTS NOT SUPPORTED**

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>36</sup> Dialysis facilities must maintain complete, accurate, and accessible records on all patients.<sup>37</sup>

The ESRD bundled payment includes a payment adjustment based on a case-mix that may take into account patient weight, body mass index, body surface area, length of time on dialysis,

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<sup>33</sup> BMA's internal policies and procedures require that any transcribed order must have a written order signed by a physician.

<sup>34</sup> *Medicare Claims Processing Manual*, chapter 8, § 10.2 and *Medicare Benefit Policy Manual*, chapter 11, § 50.A.6.

<sup>35</sup> The patient must be informed of their right to refuse or discontinue treatment (42 CFR § 494.70(a)(5)).

<sup>36</sup> The Act, § 1833(e); 42 CFR § 424.5(a)(6).

<sup>37</sup> 42 CFR § 494.170.

age, and other factors.<sup>38</sup> Medicare computes body mass index and body surface area using height and weight data reported on dialysis facilities' claims. These measures are closely associated with the duration and intensity of dialysis services needed to achieve a therapeutic target for ESRD patients.<sup>39</sup> Accordingly, inaccurate height or weight measurements could potentially result in a beneficiary receiving inappropriate dialysis treatments. Dialysis facilities are required to report hematocrit or hemoglobin levels on all dialysis claims. These readings should reflect the most recent reading that was taken before the start of the billing period.<sup>40</sup>

During seven beneficiary-months, BMA incorrectly reported the beneficiary's height in the incorrect unit of measure (i.e., inches rather than centimeters) (six beneficiary-months) and hemoglobin levels (one beneficiary-month) on the Medicare claim that were not supported by the beneficiary's medical records. As a result, BMA improperly claimed Medicare reimbursement for six beneficiary-months with incorrect reported heights and may have provided inappropriate dialysis treatments to the associated beneficiaries. While reporting inaccurate hemoglobin levels does not impact Medicare reimbursement, it may result in a dialysis patient not receiving the necessary medication.

While BMA had internal controls to ensure that height measurements were correctly recorded in medical records prior to submitting Medicare claims, the controls did not prevent BMA staff from incorrectly recording units of measure. BMA stated that these were human errors that were later corrected in the beneficiary's medical record; however, they were not corrected on the related Medicare claims.

While BMA's policies and procedures (a type of internal control) require a reconciliation between information in the medical records and the Medicare claims, these occurred because the controls were not effective in identifying discrepancies in the hemoglobin levels reported to Medicare. BMA reported hemoglobin levels on a Medicare claim that did not reflect the most recent reading documented in the associated beneficiary's medical record.

## **HOME 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>41</sup> In this respect, dialysis facilities must maintain complete, accurate, and accessible

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<sup>38</sup> The Act, § 1881(b)(14)(D)(i); 42 CFR § 413.235; and *Medicare Claims Processing Manual*, chapter 8, § 20.1.

<sup>39</sup> 75 Fed. Reg. 49030, 49034-49035 (Aug. 12, 2010); *Medicare Benefit Policy Manual*, chapter 11, § 60.A.3.

<sup>40</sup> 77 Fed. Reg. 67490, 67491 (Nov. 9, 2012); *Medicare Claims Processing Manual*, chapter 8, § 60.4.2.

<sup>41</sup> The Act, § 1833(e).

records on all patients and, as appropriate, must furnish such information to determine whether payment is due and the amount of such payment.<sup>42</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>43</sup> The facilities must retrieve and review patients' self-monitoring data and other information, and maintain it in the patients' medical records.<sup>44</sup>

During seven beneficiary-months, BMA claimed Medicare reimbursement for home dialysis services for which it did not provide documentation to support some services. Specifically, BMA did not provide treatment notes for 132 home dialysis sessions claimed during the 7 beneficiary-months. Additionally, during one of the beneficiary-months, BMA did not provide documentation to support the dispensing of a dosage of Epogen—a medication used to treat anemia.

While BMA had internal controls to monitor and maintain complete, accurate, and accessible records on all patients, BMA staff did not always follow them. As result, BMA received improper payments for home dialysis services not documented in beneficiaries' medical records. Failure to document home dialysis services demonstrates a lack of proper supervision and monitoring of the beneficiary's treatment, which could result in inappropriate or inadequate treatment.

## **CONCLUSION**

On the basis of our sample results, we estimated that BMA received unallowable Medicare payments of at least \$96,185 for our audit period. We note that, while these identified payments are not significant when compared to BMA's total Medicare reimbursements for the period, the errors we identified could have a significant impact on the quality of services that BMA is providing to Medicare beneficiaries.

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

<sup>43</sup> 42 CFR § 494.100.

<sup>44</sup> 42 CFR §§ 494.100(b)(2) and (3).



## RECOMMENDATIONS

We recommend that Bio-Medical Applications of Arecibo, Inc.:

- refund to the Federal Government the portion of the estimated \$96,185 in improper payments for claims incorrectly billed to the Medicare program that are within the reopening period;<sup>45</sup>
- for the remaining portion of the estimated \$96,185 in improper payments for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify any additional similar improper payments in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- strengthen its internal controls to ensure that plans of care and comprehensive assessments meet Medicare requirements;
- modify its internal controls to ensure that ESRD measurements are properly supported; and
- reinforce through training the application of its internal controls for physicians' orders and beneficiaries' medical records to ensure compliance with Medicare requirements.

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<sup>45</sup> OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to Department of Health and Human Services action officials. Action officials at CMS, acting through a MAC, will determine whether a potential overpayment exists and will recoup any improper payments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904 (a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An improper payment based on extrapolation is re-estimated depending on the result of the appeal.

## **BIO-MEDICAL APPLICATIONS OF ARECIBO, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, BMA, through its attorneys, did not specifically indicate concurrence or nonconcurrence with our recommendations but described actions it has taken and plans to take to address some of them. BMA generally disagreed with our findings and stated that any findings with payment implications are unsubstantiated based on additional documentation it provided under separate cover. BMA asserted that many of the issues we identified were the result of its transition from paper-based to electronic medical records. Finally, BMA stated that our sampling methodology was flawed and that there was no statistically valid use for it.

After reviewing BMA's comments and the additional documentation provided, we revised our determinations for 17 beneficiary-months and adjusted our disallowance amount and related recommendations accordingly. However, the overall number of beneficiary-months determined to be in error did not change from our draft report because these 17 beneficiary-months still contained errors. We maintain that our findings and recommendations, as revised, are valid. We also maintain that our sampling methodology was valid.

BMA's comments are included in their entirety as Appendix E.

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

#### **BMA Comments**

BMA stated that it has internal policies and controls that address Medicare requirements for documenting services; however, it acknowledged that despite these policies and controls, certain plans of care and comprehensive assessments had various documentation errors. BMA also described corrective actions it has taken subsequent to our audit period to improve its ability to prevent errors similar to those identified in our draft report. Specifically, BMA stated that it will train its nursing staff on regulatory requirements and monitor active medical records for compliance with documentation requirements.

#### **OIG Response**

As we described in the draft report, BMA's failure to ensure that plans of care and comprehensive assessments comply with Medicare requirements could result in inadequate treatment planning and could preclude beneficiaries from receiving needed services. We commend BMA for taking action to address the deficiencies identified in our draft report related to plans of care and comprehensive assessments.

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

### **BMA Comments**

BMA acknowledged that height and weight measurements are clinical parameters used in establishing the ideal treatment for dialysis patients. However, it indicated that the height and weight measurement issues identified in our draft report did not impact beneficiaries' treatments, BMA's oversight of beneficiaries' treatments, or BMA's ability to ensure that clinical records accurately reflect beneficiaries' heights and weights. Nevertheless, BMA stated that it will continue to partner with patients in training and education around the importance of home dialysis documentation.

### **OIG Response**

As we described in the draft report, inaccurate height or weight measurements could potentially result in a beneficiary receiving inappropriate dialysis treatments. We commend BMA for stressing the importance of documentation with its home dialysis patients. However, many of our errors involved in-center patients. As such, we continue to recommend that BMA modify its internal controls to ensure patients' heights are measured and recorded in the patients' charts on an annual basis, as required, and not only when there is a change in the patient's height.

## **PHYSICIANS' ORDERS NOT VALID**

### **BMA Comments**

BMA disagreed with our finding related to physicians' orders, provided additional documentation for one beneficiary-month (sample 34), and asserted that other documentation in beneficiaries' medical records could substantiate and document the need for dialysis treatment. To support its assertion, BMA provided detailed responses for three beneficiary-months, including sample 34. BMA also stated that progress notes in the medical records for these three beneficiary-months contained all the components of the dialysis order. BMA further stated that although it was not able to locate signed paper orders, does not mean that the orders did not exist. Rather, it contended that the orders identified in our draft report as unsigned were entered into its electronic recordkeeping system as "Transcribed" and that medical record documentation indicated that the services were provided.

## **OIG Response**

Based on BMA's comments and the additional documentation, we revised our determinations for three beneficiary-months,<sup>46</sup> including sample 34. However, two of these three beneficiary-months also included ESRD laboratory services and drugs for which there were no valid physician orders.<sup>47</sup> Accordingly, we are questioning 21 beneficiary-months for which the physicians' orders for ESRD laboratory services and drugs did not comply with Medicare requirements because the orders had expired, were not yet effective, or were not signed by a physician. BMA provided no evidence that these services were ordered in accordance with Medicare requirements. Noting "Transcribed" on an electronic record does not meet Medicare requirements for ordering ESRD services.

## **DIALYSIS TREATMENTS NOT COMPLETED**

### **BMA Comments**

BMA stated that there are no payment consequences when a patient's dialysis treatment does not last the prescribed length since Medicare reimbursement is not dependent upon the time period associated with the actual treatment. BMA stated that while it attempts to ensure all patients undergo their full course of dialysis treatment, in certain unforeseen circumstances, patients may seek to end a treatment session early.

### **OIG Response**

Based on BMA's comments, we revised our financial disallowance for nine claims. However, we maintain that, during these nine beneficiary-months, BMA claimed Medicare reimbursement for dialysis treatments for which it did not document a valid medical reason for discontinuing the treatment or the beneficiary's refusal of treatment. As we described in the draft report, failure to complete dialysis treatments could result in a beneficiary not receiving needed treatments and could be detrimental to the beneficiary's health. Accordingly, we are still including these claims as a quality of care issue because Medicare CfCs were not met.<sup>48</sup>

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<sup>46</sup> Specifically, we revised our determinations for dialysis services identified in our draft report as not having a signed physician's order.

<sup>47</sup> Sample 34 remains in error for other reasons.

<sup>48</sup> *Medicare Claims Processing Manual*, chapter 8, § 10.2 and *Medicare Benefit Policy Manual*, chapter 11, § 50.A.6.

## **END-STAGE RENAL DISEASE MEASUREMENTS NOT SUPPORTED**

### **BMA Comments**

BMA stated that, for the beneficiary-months identified in our draft report with incorrect height measurements, the issue was not that beneficiaries' heights were not recorded. Rather, the issue was that heights were recorded in a unit of measurement that was not recognized (i.e, inches as opposed to centimeters). BMA also noted that this issue resulted in underpayments and provided additional documentation and detailed explanations for three beneficiary-months (samples 20, 22 and 77). Additionally, BMA disagreed with our determinations for two of three beneficiary-months identified in our draft report as having unsupported hemoglobin levels and provided additional documentation related to them. Finally, BMA stated that it will continue to provide education and training on accurate documentation and measurement units.

### **OIG Response**

Based on BMA's comments and additional documentation, we revised our determination or calculated disallowance for each of the five beneficiary-months for which BMA provided detailed explanations or additional documentation.<sup>49</sup> We maintain that our finding, as revised, is valid.

## **HOME DIALYSIS SERVICES NOT DOCUMENTED**

### **BMA Comments**

BMA adamantly disputed our finding that it received improper payments for home dialysis services not documented in beneficiaries' medical records, as well as our conclusion that it represented a lack of proper supervision and monitoring of home dialysis services that could result in inappropriate or inadequate treatment. BMA stated that it relies on home dialysis patients to comply with documentation requirements because BMA staff are not present during such treatments. BMA stated that it makes a reasonable effort to obtain home treatment records; however, it cannot guarantee that home dialysis patients provide service records every month. According to BMA, any perceived gaps in documentation do not constitute payment errors, particularly when other forms of documentation may substantiate that the services were provided and medically necessary. Finally, BMA provided detailed explanations for the eight beneficiary-months identified in our draft report as containing home dialysis services that were not documented. BMA also provided additional documentation for one of these eight beneficiary-months (sample 77).

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<sup>49</sup> Specifically, for three beneficiary-months during which BMA reported beneficiaries' heights in the incorrect unit of measure, we maintain that the beneficiaries' heights were not supported; however, we revised our calculated disallowance to reflect their heights in the correct unit of measurement. We also revised our determinations for two beneficiary-months during which BMA reported hemoglobin levels that were not supported.

## OIG Response

Based on the additional documentation provided, we revised our determination for one of the eight beneficiary-months (sample 77). We maintain that, during the remaining beneficiary-months, home dialysis services were not documented in beneficiaries' medical records. Pursuant to the Act, 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>50</sup> It is the responsibility of dialysis facilities to obtain monitoring data and other information from its home dialysis patients and to maintain that documentation in the beneficiary's medical records.<sup>51</sup>

## OIG SAMPLING METHODOLOGY

### BMA Comments

BMA stated that our sampling methodology was flawed and that there was no statistically valid use for it. Specifically, BMA stated that the *Medicare Program Integrity Manual* (MPIM) provides guidance to Medicare contractors on statistical sampling and overpayment estimation. BMA alleged that our sampling and extrapolation did not meet MPIM requirements and as a result, asserted that our extrapolation was improper. BMA also alleges that our sample was improper because each individual in the sample could be associated with multiple claims.

### OIG Response

We maintain that our sampling methodology was valid. The legal standard for the use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology.<sup>52</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. Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment

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<sup>50</sup> The Act, § 1833(e) and 42 CFR § 424.5(a)(6).

<sup>51</sup> 42 CFR §§ 494.100(b)(2) and (3).

<sup>52</sup> See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at \*12 (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); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at \*13 (S.D. Tex. 2012).

amounts in Medicare and Medicaid.<sup>53</sup> We also note that the MPIM applies to Medicare contractors—not the OIG.<sup>54</sup>

The fact that individual beneficiary-months in the sample can have multiple claims associated with them does not impact the validity of the statistical estimate. The design can be described as a simple random sample of beneficiary-months or a clustered sample of claims. Regardless of the description, the same calculation can be applied to obtain an unbiased point estimate and a conservative lower limit.<sup>55</sup>

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<sup>53</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 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

<sup>54</sup> See Social Security Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, Pub. No. 100-08, ch. 8.4, § (effective January 2, 2019).

<sup>55</sup> *Sampling Techniques*, 3rd edition, Cochran, William G. (1977), *Sampling of Populations*. (Theorem 9A.1 defines the unbiased estimate for a population total calculated from a cluster design. This estimate is mathematically identical to the mean difference estimator as applied to a simple random sample of grouped items, such as beneficiary-months — see the corollary to Theorem 2.1. Similarly, the variance estimator for the simple random sample shown in Equation 2.13 is mathematically identical to the equations outlined in Theorem 9A.2 for clustered samples.)

## **APPENDIX A: AUDIT SCOPE AND METHODOLOGY**

### **SCOPE**

Our review covered 6,726 beneficiary-months for which BMA received Medicare reimbursement totaling \$11,461,195 for dialysis services provided during our audit period. A beneficiary-month was defined as all dialysis services provided to a beneficiary by BMA during 1 calendar month. Claims for these services were extracted from CMS's National Claims History (NCH) file.

We did not review the overall internal control structure of BMA. Rather, we limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of BMA's policies and procedures for documenting and billing Medicare for dialysis services. Our review 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 fieldwork at BMA's offices in San Juan, Puerto Rico.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations and guidance;
- interviewed officials from Novitas (the MAC that processed and paid the Medicare claims submitted by BMA during our audit period) to obtain an understanding of the Medicare requirements related to dialysis services;
- interviewed BMA officials to gain an understanding of BMA's 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 6,726 beneficiary-months totaling \$11,461,195 for our audit period;
- selected a random sample of 100 beneficiary-months from the sampling frame;
- reviewed data from CMS's Common Working File to determine whether claims associated with the sampled beneficiary-months had been cancelled or adjusted;
- obtained medical records and other documentation from BMA for the 100 sampled beneficiary-months;



- reviewed the medical records and other documentation provided by BMA to support the sampled beneficiary-months;
- submitted the medical records and other documentation to an independent medical review contractor who 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 beneficiary-month did not comply with Medicare requirements;
- used the results of the sample to estimate the amount of improper Medicare payments made to BMA for dialysis services; and
- discussed the results of our review with BMA 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>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>	04/30/2014
<i>Compliance Review of Lowell General Hospital's Methuen Dialysis Facility</i>	<a href="#"><u>A-01-12-00517</u></a>	02/06/2014

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

### **TARGET POPULATION**

The population consisted of all Medicare Part B beneficiary-month claims for which BMA received Medicare reimbursement during CYs 2015 through 2016 (audit period).<sup>56</sup> A beneficiary-month was defined as all ESRD services provided to a beneficiary by BMA during 1 calendar month.

### **SAMPLING FRAME**

The sampling frame was an Access database containing 6,726 beneficiary-months (6,971 claims) with payments totaling \$11,461,195 for ESRD services provided during our audit period. The claims data were extracted from CMS's NCH file.

### **SAMPLE UNIT**

The sample unit was a beneficiary-month.

### **SAMPLE DESIGN**

We used a simple random sample.

### **SAMPLE SIZE**

We selected a sample of 100 beneficiary-months.

### **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 beneficiary-months in the sampling frame from 1 to 6,726. After generating 100 random numbers, we selected the corresponding frame items.

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<sup>56</sup> Claims excluded in the Recovery Audit Contractor data warehouse and reviewed by the MAC have been removed from the target population.

## **ESTIMATION METHODOLOGY**

We used the OAS statistical software to estimate the total amount of overpayments paid to BMA for unallowable ESRD services. 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 improper payment total 95 percent of the time. We also used the software to calculate the corresponding point estimate and upper limit of the 90-percent confidence interval.

## APPENDIX D: SAMPLE RESULTS AND ESTIMATES

### Sample Results

Beneficiary-Months in Frame	Value of Frame	Sample Size	Value of Sample	Number of Beneficiary-Months With Errors in Sample	Value of Unallowable Beneficiary-Months in Sample
6,726	\$11,461,195	100	\$167,918	96 <sup>57</sup>	\$6,678

### Estimated Value of Unallowable Beneficiary-Months (Limits Calculated for a 90-Percent Confidence Interval)

Point Estimate	\$449,142
Lower Limit	96,185
Upper Limit	802,099

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<sup>57</sup> While 96 beneficiary-months contained services with an error, services during only 12 of the 96 beneficiary-months impacted BMA's Medicare reimbursement.

## APPENDIX E: BIO-MEDICAL APPLICATIONS OF ARECIBO, INC., COMMENTS

# Morgan Lewis

**Susan Felgin Harris**  
Partner  
+1.713.890.5733  
susan.harris@morganlewis.com

December 2, 2019

**VIA OVERNIGHT DELIVERY AND ELECTRONIC MAIL to [nicholas.halko@oig.hhs.gov](mailto:nicholas.halko@oig.hhs.gov)**

Ms. Brenda M. Tierney  
Regional Inspector General for Audit Services  
U.S. Dep't. of Health & Human Services, Office of Audit Services Region II  
Jacob K. Javitz Federal Building  
26 Federal Plaza, Room 3900  
New York, NY 10278

Re: Bio-Medical Applications of Arecibo, Inc.;  
Response to Audit Report A-02-17-01016

Dear Ms. Tierney:

Bio-Medical Applications of Arecibo, Inc., ("BMA Arecibo"), through its counsel, Morgan, Lewis & Bockius LLP, submits this letter in response to the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General's ("OIG") draft audit report (A-02-17-01016), entitled *Medicare Dialysis Services Provider Compliance Review: Bio-Medical Application of Arecibo, Inc.*, dated October 18, 2019 (the "Draft Report").

### I. INTRODUCTION

BMA Arecibo is a subsidiary of Fresenius Medical Care Holdings, Inc., d/b/a Fresenius Medical Care North America ("FMCNA"), which is a health care company focused on delivering the highest quality care to people with renal and other chronic conditions. Since its formation, FMCNA has grown into the largest vertically integrated dialysis provider in North America and its employees are dedicated to the mission of delivering superior care that improves the quality of life for people with kidney disease, including end-stage renal disease, better known as kidney failure. FMCNA owns, operates, or provides administrative services to over 2,400 dialysis clinics in the United States, serving approximately 200,000 patients. In Puerto Rico, FMCNA serves approximately 4,150 patients at 30 dialysis clinics across the Commonwealth.

The Draft Report reviews the furnishing of dialysis performed in the outpatient and home setting. Home dialysis includes two types of peritoneal dialysis for which BMA Arecibo provides home dialysis training and support services: (1) continuous ambulatory peritoneal dialysis (CAPD); and (2) continuous cycler peritoneal dialysis (CCPD). The Draft Report includes a review of claims from four BMA Arecibo corporate entities that operate 30 dialysis centers located in Puerto Rico. The

#### Morgan, Lewis & Bockius LLP

1000 Louisiana Street  
Suite 4000  
Houston, TX 77002  
United States

+1.713.890.5000  
+1.713.890.5001

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audit period covers claims for services provided during January 1, 2015 through December 31, 2016 (Audit Period). The audit reviewed a sample of 100 beneficiary months. Claims and medical records were submitted for review to an independent medical review contractor.

The Draft Report identified six (6) "Findings." BMA Arecibo does not agree with the findings, as set forth more particularly below. In addition, with regard to those findings that implicate payment and identify a purported overpayment, BMA Arecibo believes the findings are unsubstantiated based on further evidence and documentation provided. BMA Arecibo respectfully requests that the OIG review and reconsider its conclusions with the benefit of the information provided in this response prior to issuing its final report.

## **II. RESPONSE TO DRAFT REPORT FINDINGS**

BMA Arecibo has reviewed the Draft Report and provides the response below to each Finding. Many of the identified issues do not result in any payment impact, but may, for example, focus on processes and training that were the result of transitions from paper to electronic recordkeeping. BMA Arecibo appreciates the comments and will review and conduct training as appropriate.

### **Finding #1: Some Plans of Care and Comprehensive Assessments Had Documentation Errors.**

Finding #1 involves documentation errors and includes two components: (1) identified instances of noncompliance involving the documentation and elements associated with the completion of patient Plans of Care; and (2) a lack of documentation details, timely completion, and signatures for patient Interdisciplinary Team Comprehensive Assessments.

An Interdisciplinary Team is responsible for providing dialysis patients 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, as well as the beneficiary. The comprehensive assessment and plans of care are conducted annually for stable patients and at least monthly for unstable patients.

BMA Arecibo has policies and internal controls that address these requirements and include such processes and procedures in its training programs. Notwithstanding these controls, certain plans of care and comprehensive assessments had various documentation errors identified by the OIG Report.

Since 2018, BMA Arecibo has implemented and periodically upgraded its electronic Plan of Care (ePOC) software to enhance the entire electronic interface for clinical systems relating to Plans of Care. This ePOC was implemented on May 6, 2018. The implementation of the ePOC application enhances coordination and collaboration of the Interdisciplinary Team in being able to track patient-centric Plans of Care and in enhancing the accuracy of documentation by automating tasks related to a patient's Plan of Care, such as calculating due dates for the Comprehensive Interdisciplinary Team (CIT) meetings, and allowing physicians and other members of the team to use electronic signatures. Thus, the ePOC replaces manual scheduling and provides accurate tracking of the patient's Plan of Care.

In addition, BMA Arecibo has developed additional reference tools related to the Comprehensive Assessment, and notes that the following actions are being implemented to assure that BMA

Arecibo staff and all providers are reminded of the importance of documenting all elements of the Plans of Care and Comprehensive Assessment:

- All nursing staff will undergo an in-service program designed to review regulatory requirements and internal policies related to the completion of the Comprehensive Assessment and Plan of Care.
- For the next 6 months the facility's Quality Assessment and Performance Improvement process will review a sampling of active medical records to monitor improved compliance with Comprehensive Assessment and Plan of Care documentation requirements.

We appreciate the Draft Report noting the issue. BMA Arecibo believes that the improvements it has made to its operations since the time of the audit have further improved its ability to document Plans of Care and Comprehensive Assessment.

**Finding #2: Some Height and Weight Measurements Were Not Timely Recorded.**

Finding #2 includes deficiencies related to: 1) height measurements not documented as taken within the 1-year requirement; and 2) weight measurements not taken immediately following the last home dialysis session of the month.

Height and weight measurements are clinical parameters used in establishing the ideal treatment for a dialysis patient. Peritoneal dialysis requires partnering with the patient as it is, by definition, self-care, typically completed daily by the patient in his/her home without the direct involvement of facility staff. This modality allows many patients diagnosed with End Stage Renal Disease (ESRD) to continue to work, travel and generally enjoy more independence while undergoing dialysis. The patient is monitored and supported by the ESRD facility. The role of the facility staff is to provide training, education and monitoring. As self-care individuals, patients receive education upon admission, and continuing education regarding the importance of documenting their treatment. However, facility staff does not assist and generally is not present during treatments. Facilities, therefore, must rely on the patient to comply with the documentation requirements.

While BMA Arecibo appreciates the OIG Report's identification of issues for continuous improvement, these findings do not have an impact on a beneficiary's receipt of dialysis, our oversight of the treatment, or the ability through the remaining information that is part of an ongoing clinical record to ensure that the height and weights for the patient are correct. We can and do always seek to review internal processes to determine if there are opportunities for improvement and assure accurate documentation. However, with regard to the delivery of home dialysis, beneficiaries also have obligations in their own care, including the requirement to obtain and document their weight during each of their home treatments and to provide treatment sheets to their dialysis provider. BMA Arecibo will continue to partner with patients in training and education around the importance of documentation.

Since 2017, BMA Arecibo has further enhanced its clinical systems relating to home patient documentation, including upgrading the portal such that patients can more easily enter their treatment information. BMA Arecibo also endeavors to provide home treatment logs for those patients who do not or cannot use an electronic portal system. BMA Arecibo trains patients relating to monitoring their blood pressure, solution selection, medications and compliance with their individual treatment regimen, along with providing flowsheets to capture their CAPD or CCPD

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treatment information.

We appreciate the Draft Report noting the issue. BMA Arecibo will continue to emphasize the need for this element in all of our training modules moving forward.

**Finding #3: No Physician Orders or Orders Not Signed.**

Finding #3 involves instances noted in which either the physician order for dialysis treatments, laboratory services and drugs had: 1) expired and/or were inactive; or 2) was not signed.

Specifically, the Draft Report found that reimbursement was claimed during 8 beneficiary months for which a physician's order had expired when the services were provided and during 2 beneficiary months for which the physician's order was not yet effective. Additionally, the Draft Report noted 14 beneficiary months during which physician orders were not signed.

The provision of dialysis is an essential aspect of care for an individual with ESRD. BMA Arecibo takes this role in the delivery of patient care seriously and seeks to ensure that its patients receive the life-saving care they need, while also assuring that it complies with all the documentation required to support and substantiate the delivery of that care.

BMA Arecibo disagrees with the Draft Report finding. First, during this audit time period, BMA Arecibo clinics were transitioning from a paper-based documentation system to an electronic-based documentation system. While the exact document sought by the auditor may not have been readily located, it does not mean that the service was not authorized by a physician. Where BMA Arecibo has been able to identify or locate a physician order not found at the time of the audit, we have submitted it to the OIG. For example, additional documentation has been submitted for sample # 34.

Moreover, a number of other documents, notes, and provider-related support appear in medical records to substantiate the ongoing delivery of life-saving dialysis treatment that support the delivery of care for the samples and physician orders identified in the OIG Report.

The regulation at 42 CFR § 424.24(g) provides that the "physician, nurse practitioner, clinical nurse specialist, or physician assistant may provide certification at the time the services are furnished or, if services are provided on a continuing basis, either at the beginning or end of a series of visits.... Recertification of continued need for services is not required." *Id.* Thus, a provider's signature is not required for orders reflecting services that are provided on a continuing basis, such as dialysis. Further, the CMS Manual provides that "other regulations and the CMS' instructions regarding the conditions of payment related to signatures (such as timeliness standards for particular benefits) takes precedence. *CMS Publication 100-08, Medicare Integrity Manual, Chapter 3 § 3.3.2.4.* In cases where the relevant regulations, National Coverage Determinations, Local Coverage Determinations or CMS manuals have specific signature requirements, those signature requirements take precedence." *Id.* (see Exception 3).

Finding #3 is not indicative of an overall failure of documentation or of quality of care in assuring that services are timely and appropriately delivered. Rather, the Finding identifies a documentation issue which can be explained, in large part, by the transition between paper and electronic medical record.

The patient record usually contains documentation beyond the physician orders. For example, the

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CMS Form 2728, Provider Comprehensive and Rounding Notes, Interdisciplinary Assessments and Plans of Care, hospital summaries, documentation of co-morbidities and other documentation of conversations with the physician, staff and Interdisciplinary Team members all appear in a medical record and substantiate and document the need, plan and schedule for the receipt of dialysis treatment. As noted above, since the time of this audit, BMA Arecibo completed implementation of the electronic system, referred to as eCube.

In addition, during the time frame of this audit, the BMA Arecibo clinics were transitioning from paper records to electronic records. As part of this transition, the nurse took the signed paper order from the physician and entered it into the electronic clinical system as "transcribed." The orders that have been identified as unsigned in this audit are all orders that were transcribed. While the facility was not able to locate the underlying paper-based order in the record in response to this audit, this does not mean that the order did not exist. Rather, medical record documentation establishes that the provider ratified the order for services provided on the dates in question as outlined below for each of the samples.

Accordingly, denial of payment based on this finding is unwarranted, as the service was delivered; contemporaneous documentation substantiates the need for the service; information about the medical necessity and factors associated with the delivery of service is included in the medical record; and the Medicare program itself, as noted above, recognizes that other forms of documentation may be used and relied upon in documenting such service.

Pursuant to the ESRD Prospective Payment System (PPS), modifications to certain components of the dialysis order do not impact the reimbursement for treatment. Similarly, modifications that a physician may make to the order for dialysis treatment do not impact reimbursement under the ESRD PPS. Thus, failing to meet certain conditions of coverage do not automatically result in payment suspension. Here, the services were provided, and all ancillary and contemporaneous documentation support the delivery of such services. As CMS itself emphasized, "NOTE: Conditions of participation (COP) are not conditions of payment." 100-08 Medicare Program Integrity, Transmittal 751, Change Request 10322, dated October 20, 2017, page 4.

In addition to the above comments, specific responses to individual sample items are as follows:

**Sample 34 (7/1/15 – 7/31/15)**

With regard to this Sample, the physician entered and authenticated a dialysis treatment order on 12/10/2014 (ref. doc #3366RA0323). Under 42 CFR § 424.24(g)(4), a signature for subsequent revisions is not required. Subsequent changes to this order were related only to components of the dialysis order, not the medical necessity of the dialysis treatment itself. Progress notes documented by the physician contain all components of the order in question; namely, the progress notes contain the hemodialysis prescriptions during the stated time period, which are signed by the provider as an affirmation of those prescriptions (ref. docs: 7/1/15 #3366RAS0054-0055; 7/8/15 #3366RAS0047-0053; 7/15/15 #3366RAS0056-0057; 7/20/15 #3366RAS0058-0059; and 7/22/2015 #3366RAS0060-0061). In addition, BMA Arecibo located the physician order not found at the time of the audit, which was submitted to the OIG on November 8, 2019 (ref. doc: # 3366RA0328).

**Sample 44 (7/2/15-7/30/15)**

The hemodialysis order was entered and authenticated by the physician on 6/19/2014 (ref doc #3366RTT0287). Subsequent modifications to this order were related only to components involving dialysis, such as a modification to dialyzer flow rate for example, rather than the medical necessity of the dialysis treatment itself. Progress notes subsequently documented by the physician contain all components of the orders in question; namely, the progress notes contain the hemodialysis prescriptions during the stated time period and are signed by the provider as an affirmation of those prescriptions. (ref. docs: 7/2/15 #3366RTT0040-041; 7/9/15 #3366RTT0033-0039; 7/16/15 #3366RTT0042-0043; and 7/23/15 #3366RTT0044-0045).

**Sample 82 (3/3/15-3/31/15)**

The hemodialysis order was entered and authenticated by the physician on 6/19/2014 (ref doc #3366RTT0287). Progress notes subsequently documented by the physician contain all components of the orders in question; namely, the progress notes contain the hemodialysis prescriptions during the stated time period and are signed by the provider as an affirmation of those prescriptions. (ref. docs: 3/5/15 #3366RTT0031-0032; 3/12/15 #3366RTT0024-0030; 3/19/15 #3366RTT0033-0034; and 3/26/15 #3366RTT0035-0036).

**Finding# 4: Dialysis Treatment Not Completed.**

The OIG's recommended remedy for Finding #4 is incongruent both with the payment methodology for dialysis and the alleged treatment issues identified by the OIG at BMA Arecibo. As noted by the OIG in its report, the discontinuation of dialysis treatment is rare and should be medically justified. This is juxtaposed by the requirement that all beneficiaries are informed of the right to refuse or discontinue treatment, as set forth in the regulations, 42 CFR § 494.70 (a)(5). While BMA Arecibo attempts to ensure all patients undergo their full course of dialysis treatment, in certain unforeseen circumstances, patients may seek to end a session of treatment early.

In terms of addressing such unforeseen circumstances, BMA Arecibo has a robust patient education program, which includes education on the importance of adherence to treatment time. Clinic staff work with patients to address potential problems that may interfere with their ability to adhere to treatment time. Moreover, our policy "Early Termination or Arriving Late for Treatment" specifically calls for counseling and education on effects of shortened treatment. The Interdisciplinary Team (IDT) at the ESRD facility closely monitors patient compliance with the patient's prescribed treatment and addresses any concerns with staff and patients.

There is no payment consequence for these 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. Dialysis is a prescription-based service and the Medicare payment for ESRD under the PPS has been established as a per dialysis treatment. The base rate payment is the same regardless of the length of treatment.

The existence of the bundled rate accounts for the fact that the costs of providing the ordered treatment are incurred at the time the treatment is initiated. Therefore, the cost of the procedure is the same regardless of whether the session runs its full course or is terminated early due to non-compliance by the patient or an unforeseen medical issue, such as difficulties with access or blood pressure. Here, BMA Arecibo incurred the full cost of treatment for each of the patients identified

in the draft report regardless of when the treatment for those patients ended.

Quality of patient care at BMA Arecibo is financially incentivized by the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008. MIPPA establishes quality incentives for facilities furnishing renal dialysis services. The ESRD Quality Incentive Program (QIP) was designed to promote high-quality care by outpatient dialysis facilities treating patients with ESRD and links a portion of the dialysis payment to the facilities' performance on quality care incentives. Facilities not meeting the required measures of the QIP in any performance year may be subject to reduced payments. Hence, the QIP addresses this finding and there is no basis for any payment adjustment.

**Finding #5: End Stage Renal Disease Measurements Not Supported.**

The OIG Report identified 9 beneficiary months during which BMA Arecibo incorrectly reported the beneficiary's height in the incorrect unit of measurements (*e.g.*, in inches rather than centimeters) (6 beneficiary months), or hemoglobin levels (for 3 beneficiary months).

The bundled payment includes a case-mix methodology that takes into account body mass index, surface area, and age and other factors. The issue is not that the height was not recorded, but rather that it was recorded in a unit of measurement that was not recognized. Thus, the measurement requirement was met, but it was reported in inches rather than centimeters in some cases. BMA Arecibo will provide continued education and training on accurate documentation and measurement units.

In addition to the above comments, BMA Arecibo notes that this issue has resulted in underpayments and provides the following specific responses to individual sample items.

**Sample 20 (11/14-11/30/15)**

A height assessment of 57.00 (initially documented in inches) was entered on 8/4/15. The patient's correct height was 170 cm and the records were subsequently corrected.

**Sample 22 (6/9-6/18/15)**

A height assessment of 58.00 (initially documented in inches) was entered on 6/9/2015. The patient's correct height was 147 cm and the records were subsequently corrected. The OIG determined an overpayment of \$34.72 for this claim. In review of this claim, based on the correct height for this patient, the payment should have been \$841.26. The actual payment received for this claim was \$750.30, resulting in an underpayment of \$90.96. The supporting documentation for this claim was provided to the OIG on November 22, 2019 (ref doc #s 3366HDS0101-3366HDS0104).

**Sample 77 (4/28-4/30/15)**

A height assessment of 153 cm was entered on 2/6/2015. The patient's correct height was 168 cm and the records were subsequently corrected. In review of this claim, based on the correct height for this patient, the reimbursement to BMA Arecibo would have been \$535.51. The actual payment received for this claim was \$514.23, resulting in an underpayment of \$21.28. The supporting documentation for this claim was provided to the OIG on November 22, 2019 (ref doc #s 3367JSC0469-3367JSC0471).

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ESRD providers are also required to report the patient Hemoglobin (Hgb) reading taken during the billing cycle. More specifically, value code 48 represents the patient's most recent hemoglobin reading taken before the start of the billing period. For patients just starting dialysis, we utilize the most recent value prior to the onset of treatment.

We disagree with the OIG reported findings for two of the samples with Hemoglobin reporting discrepancies and provide the following:

**Sample 32 (7/20-7/29/2016)**

This patient was a transient at this facility. The most recent Hgb value for this patient taken before the start of the billing period was 10.1 which is the value that was reflected on the claim (1/31/18 ref doc: 3366JP0055). Additional supporting documentation was provided to the OIG on November 22, 2019 (ref doc # 3366JP0066).

**Sample 65 (7/14-7/30/2016)**

This patient was a transient at this facility. The most recent Hgb value for this patient taken before the start of the billing period was 10.4 which is the value that was reflected on the claim (3/12/18 ref doc: 1394HS0090). Additional supporting documentation was provided to the OIG on November 22, 2019 (ref doc # 1394HS0114).

**Finding #6: Home Dialysis Services Not Documented.**

The Draft Report suggests that BMA Arecibo received improper payments for home dialysis services not documented in beneficiaries' medical records, concluding that it represented a lack of proper supervision and monitoring for home dialysis, which could result in inappropriate or inadequate treatment.

BMA Arecibo adamantly disputes this conclusion.

When kidneys fail, waste products such as urea and creatinine build up in the blood. One way to remove these wastes is peritoneal dialysis (PD), which uses the lining of the abdomen to filter waste from the blood. Many experts agree that home dialysis is the best option for treating kidney failure whenever possible because choosing at-home dialysis can mean greater scheduling flexibility, fewer food restrictions and better quality of life and outcomes for the patient.

During peritoneal dialysis, a mixture of dextrose (sugar), salt, and other minerals dissolved in water, called dialysis solution, is infused into the patient's abdominal cavity through a catheter. There are two types of peritoneal dialysis, which differ mainly in the schedule of exchanges. In CAPD, the patient manually instills the dialysis fluid into the abdominal cavity through their catheter. The fluid is held in the abdomen for a prescribed period of time, called the "dwell." The patient then drains the abdominal solution, which contains excess fluid and wastes transported from the body into the PD solution, which would normally be eliminated in the urine. The patient then repeats the cycle. Each cycle of draining and refilling is called an exchange. A typical prescription for CAPD requires three or four exchanges during the day and one long overnight dwell time as the patient sleeps. CCPD is an automated form of peritoneal dialysis that uses a machine to fill and empty the abdomen three to five times during the night while the person sleeps.

In a clearance test, samples of used solution drained over a 24-hour period are collected, and a blood sample is obtained during the day when the solution is collected. The amount of urea in the solution is compared with the amount in the blood to see how effective the current PD schedule is in clearing the blood of urea. If the patient has more than a few ounces of urine output per day, the urine may also be collected during this period to measure its urea concentration. From the used solution, urine, and blood measurements, one can compute a urea clearance, called Kt/V, and a creatinine clearance rate. Based on these measurements, one can determine whether the PD dose is adequate. If laboratory results show that the dialysis schedule is not removing enough urea and creatinine, the doctor may change the prescription.

As noted above, home dialysis is self-care that is monitored and supported by the ESRD facility. This modality allows many patients to continue to work, travel and generally enjoy more independence while undergoing dialysis. Treatment is typically completed daily by the patient in his/her home without the direct involvement of facility staff.

The role of the facility staff is to provide training, education and monitoring and BMA Arecibo staff provide such education upon admission and on a continuing basis. As self-care individuals, BMA Arecibo staff is not present during treatments and must rely on the patient to comply with the documentation requirement.

While BMA Arecibo makes a reasonable effort to obtain home treatment records, it cannot guarantee that patients bring their home records to the clinic or terminate treatment simply because the patient did not bring in records for each month.

CMS recognized this issue in its regulations, when responding to comments, concerning the fact that home patients do not always provide documentation regarding their care at home, and that non-compliant patients may not provide the required data and other information necessary for staff to carry out the mandatory review.

Specifically, the Medicare Claims Processing Manual provides:

Under the Composite Rate, CAPD and CCPD are furnished on a continuous basis, not in discrete sessions and, therefore, are paid on a weekly or daily basis, not on a per treatment basis. Billing instructions require providers to report the number of days in the unit's field. A facility's daily payment rate is 1/7 of three times the composite rate for a single hemodialysis treatment.

The equivalent weekly or daily IPD or CAPD/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.

All home dialysis support services, equipment and supplies necessary for home IPD or CAPD/CCPD are included in the composite rate payment. No support services, equipment or supplies may be paid in addition to the composite rate.

Effective for claims with dates of service on or after April 1, 2007, line item billing is required for all dialysis sessions. For claims billing for Continuous Ambulatory

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Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD), the provider may submit a separate dialysis line for each day of the month. If the provider is aware of an inpatient stay for the beneficiary within the month, the RDF may include the date of admission and date of discharge as a billable day for the dialysis but should omit the dates within the inpatient stay. In the event that the RDF is unaware of an inpatient stay during the month, the Medicare system shall detect the overlapping dates and reject only the line item dates within the inpatient stay but pay the remainder of the claim for any dates that are not within the inpatient stay.

CMS Chapter 8 Claim Processing, Section 80.4 - Calculating Payment for Continuous Ambulatory Peritoneal Dialysis (CAPD) and Continuous Cycling Peritoneal Dialysis (CCPD).

Finally, denying reimbursement here runs counter to the government's desire to move patients from in-center to home dialysis. Indeed, the President's July 22, 2019 Executive Order seeks to incentivize the greater use of home dialysis for Medicare beneficiaries on dialysis.<sup>1</sup> This mandate is in stark contrast with the Draft Report, which creates strong disincentives for home dialysis by penalizing dialysis providers for patients' failure to submit home treatment records, a situation which CMS has recognized is beyond the facility's control.

The documentation provided demonstrates the adequacy of dialysis and indicates evidence of the care, monitoring, and management of the patient by the Interdisciplinary Team. There is no basis for payment denial. Any perceived gaps in documentation for home dialysis patients do not constitute payment errors. There is no basis to conclude that the absence of a specific item of documentation renders a claim non-payable - particularly in cases where other forms of documentation are enough to substantiate that the services billed were provided and medically necessary.

In addition to the above comments, specific responses to individual sample items are as follows.

**Sample 77 (4/28/15-4/30/15)**

During the time frame of April 28 – 30, 2015, this patient was receiving CCPD training at the dialysis facility. During training, the RN documents the steps taken to educate the patient, which includes an exchange of peritoneal dialysis solution, along with other components of self-dialysis. Exchanges completed during the training session are generally documented by the nurse. Patient documentation during training generally includes acknowledgements of the components covered during the training sessions. The physician order for peritoneal dialysis training along with the RN training records, clinical notes and patient acknowledgements have been provided (#3367JSC0442-0456, #3367JSC0463-0468, #3367JSC0053-0055).

In addition to the documentation already provided to the OIG, we have attached Exhibit A, which reflects several of the metrics utilized to assess adequacy of dialysis along with

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<sup>1</sup> Executive Order on Advancing American Kidney Health; July 10, 2019:  
<https://www.whitehouse.gov/presidential-actions/executive-order-advancing-american-kidney-health/>



references to documentation in the patients' medical record. The Exhibit demonstrates monitoring and management of the patient by the Interdisciplinary Team and illustrates that the patient record supports the adequacy of dialysis.

**Sample 15 (Date of service 2/2/15)**

During the audit month, all treatment data was provided except for one day, 2/2/15. Documentation in the Provider Rounding Note entered on 2/13/2015 (3367ER0022-0028) confirms that this patient's blood pressure and pulse rates remained consistent through February. Additionally, the patient was seen in the clinic on 2/3/2015 by the RN (3367ER0031 -0052). The note confirms that the patient's vital signs were stable with no signs of fluid overload or edema.

**Sample 20 (Dates of service 11/14/15-11/30/15)**

This patient began CCPD on November 14, 2015 following 3 months of incenter hemodialysis. The patient's weight remained stable with the prescribed dry weight unchanged. MD and RN progress notes indicated that the patient's blood pressure and pulse rates remained consistent. Additionally, the patient was seen in the clinic on 11/19/2015. The MD Notes (3366DG0258-0265) "the patient is doing well, with some leg edema under evaluation". The patient was discharged from the clinic on 12/8/2019 before his next scheduled clinic visit in which the treatment sheets would have been reviewed.

**Sample 26 (Dates of service 5/1/15-5/13/15)**

During the three-week period the patient was receiving treatment, weights remained consistent at 71 kg, with the prescribed dry weight unchanged at 71 kgs. These stable weight measures are consistent with a patient's adherence to their treatment prescription. In addition, the Provider History and Physical Note entered on 5/4/2019 (3366JAP0162-0167) confirms that the patient's vital signs were stable with no signs of fluid overload or edema.

**Sample 28 (Dates of service 11/1/16-11/14/16, 11/16-11/19/16 and 11/21-11/30/16)**

Treatment documentation for this patient was provided for 11/15, 11/20 and 11/21/16. For the one month within the audit time period, weight measures remained consistent and indicate the patient's adherence to their treatment prescription. As documented in the RN progress note entered on 11/16/2016 (3366LCV0034-0035) this patient's systolic blood pressure was elevated in November. The nurse attributed the patient's blood pressure variation to the patient's inconsistency with adherence to blood pressure medications and not necessarily as an indicator of poor treatment adherence.

**Sample 47 (Dates of service 4/1 - 4/8/15, 4/10/15, 4/12-4/28/15, 4/30/15)**

Treatment documentation was provided for 4/9, 4/11 and 4/29/15. During the 1-month period within the audit timeframe, weights taken during the patient's visits to the facility ranged from 109.77 kgs to 110.66 kgs, with the prescribed dry weight unchanged at 112 kgs. These stable weight measures are consistent with a patient's adherence to their treatment prescription. As documented in the Provider Rounding Note entered 4/29/2015 (13366RRS0017-0024) this patient's blood pressure and pulse rates remained consistent through April. Additionally, the



patient was seen in the clinic on 4/20/2015 and 4/29/2015 (13366RRS0025 – 0068) by the RN. These notes confirm that the patient's vital signs were stable with no signs of fluid overload or edema

**Sample 83 (Dates of service 6/1 – 6/30/16)**

Treatment sheets were provided for 6/1-6/7/16 for this patient. During the 1 month within the audit timeframe, weights taken during the patient's visits to the facility ranged from 81.0 kgs to 82.7 with the prescribed dry weight during the audit period consistent at 80.4 kgs. These stable weight measures are consistent with a patient's adherence to their treatment prescription. As documented in the 6/10/2016 Provider Rounding Note (3366JRP0020-0027) this patient's blood pressure and pulse rates remained consistent between from through the audit period.

**Sample 85 (Dates of service 3/1 – 3/31/16)**

Treatment sheets were provided for 3/1-3/7/16 for this patient. During the 1 month within the audit timeframe, weights taken during the patient's visits to the facility ranged from 75.45 kgs to 75.9 kgs with the prescribed dry weight during the audit period consistent at 85.45 kgs. This dry weight was adjusted in April to 77.72 to reflect the patient's consistent dry weights as measured. These stable weight measures are consistent with a patient's adherence to their treatment prescription. As documented in the Provider Rounding Note entered on 3/9/2016 (1394ISV0016-0022) notes, this patient's blood pressure and weight gains remained consistent and acceptable.

**IV. EXTRAPOLATION AND SAMPLING CONCERNS**

In addition to the comments above related to the findings in the Draft Report, BMA Arecibo notes that the sampling and extrapolation employed by the OIG in this matter is flawed and the extrapolated alleged payment adjustment is not supported.

The OIG failed to meet key requirements for a probability sample, which are required for the use of extrapolation. Based on the information provided, there is no statistically valid use for the extrapolated overpayment amount in this audit.

The Medicare Program Integrity Manual (MPIM) provides guidance to Medicare contractors in statistical sampling and overpayment estimation, and to analyze the validity of the sample and extrapolation amount in a review. The sampling and extrapolation details furnished to BMA Arecibo by the OIG reflect that the OIG has not meet the MPIM requirements. For example, the OIG applied an improper sampling methodology that included multiple claims per beneficiary causing the claims to be related. A probability sample requires proper randomization. The auditor failed to use the proper method for a simple sample of dependent observations. In addition, the auditor failed to address outliers or stratification, and the error rate is below 50% which the MPIM indicates should not be extrapolated.

We note a few of the reasons why the extrapolation is improper. BMA Arecibo would be happy to further discuss these issues with the OIG. In sum, any extrapolation is unsupported under Medicare requirements.

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Ms. Brenda M. Tierney  
December 2, 2019  
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**V. CONCLUSION**

BMA Arecibo appreciates the opportunity to provide comments to the OIG for its consideration and inclusion in its final audit report. We request that OIG consider the information contained in these comments and the supplemental information, and modify its Report findings accordingly.

Sincerely,

A handwritten signature in blue ink, appearing to read "Susan Feigin Harris".

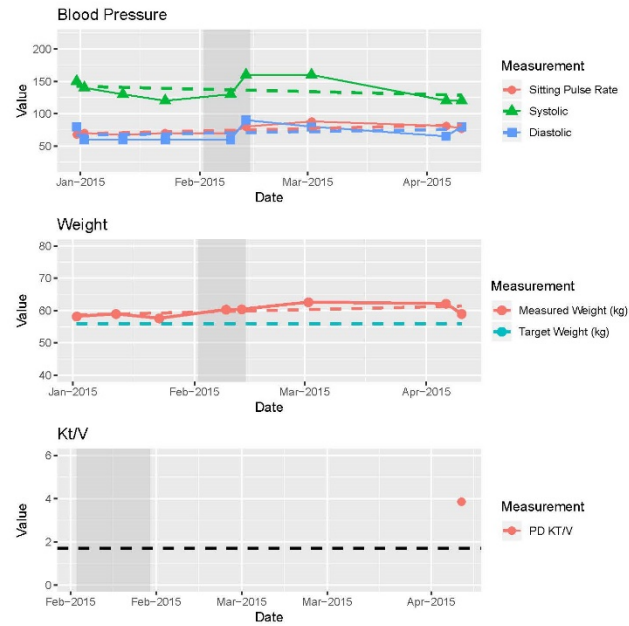
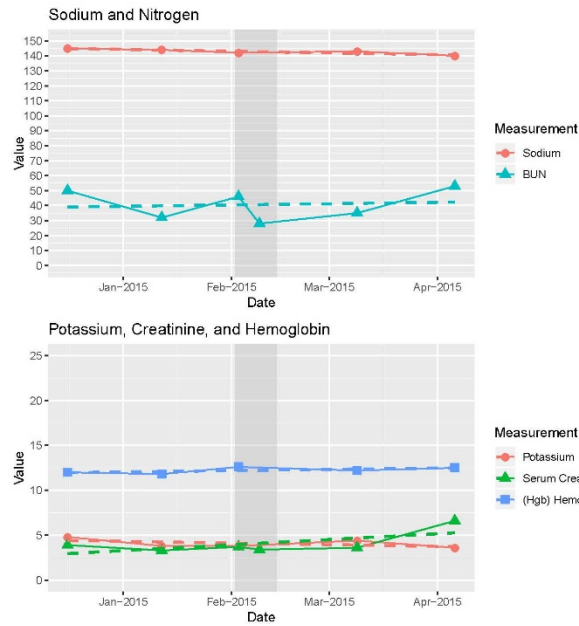
Susan Feigin Harris

cc: William Harb, Esq. (BMA Arecibo)  
Timothy Saunders, Esq. (BMA Arecibo)  
Scott McBride, Esq. [Firm]

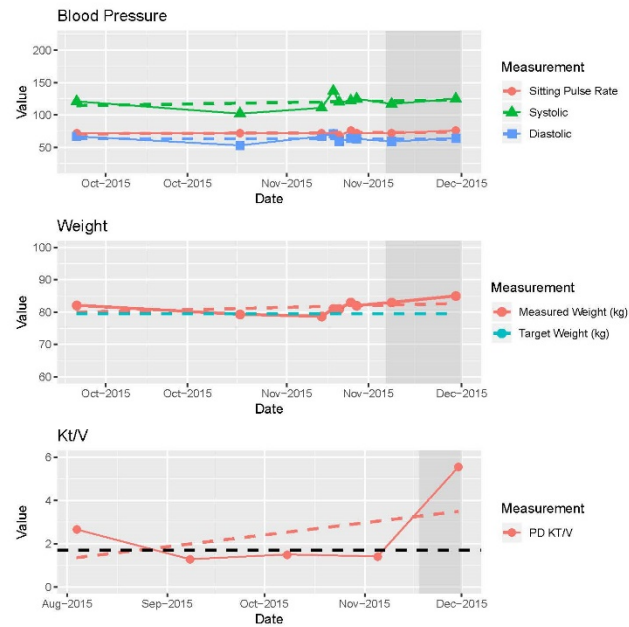
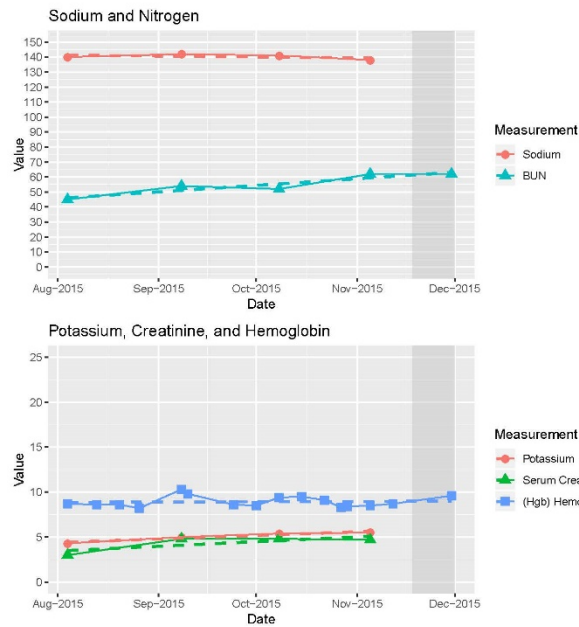
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# **EXHIBIT A**

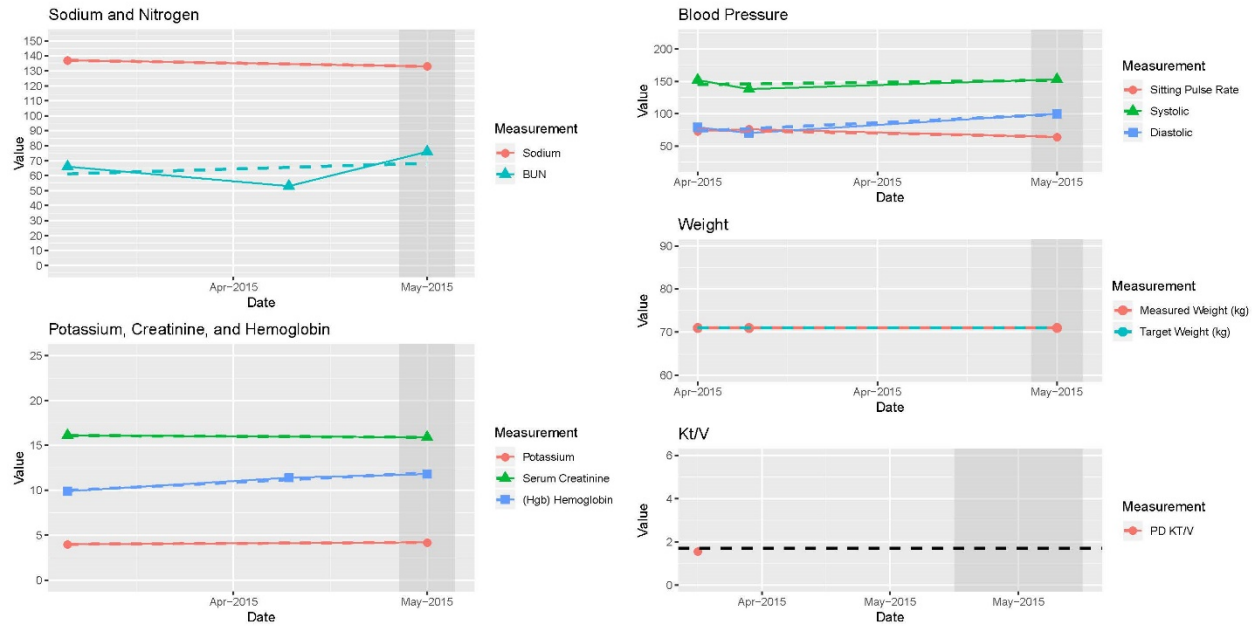
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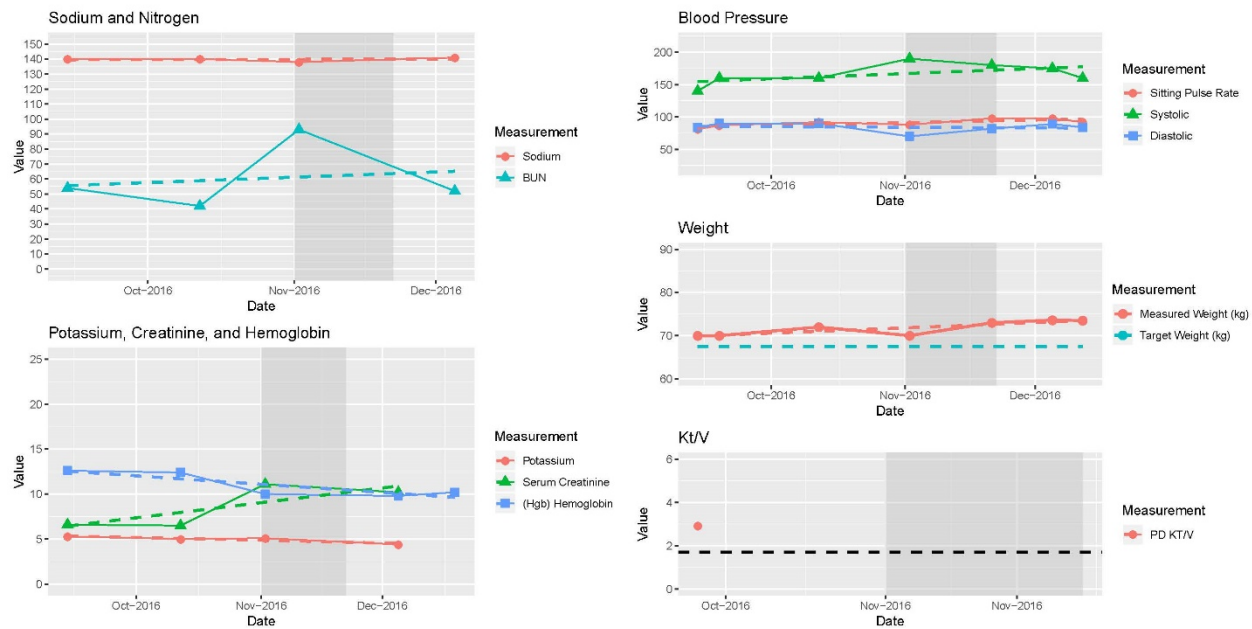
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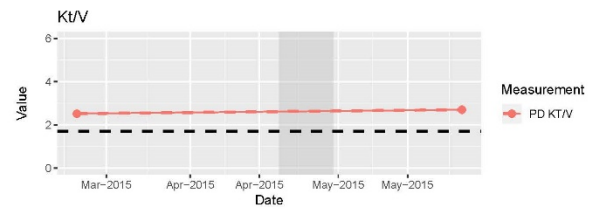
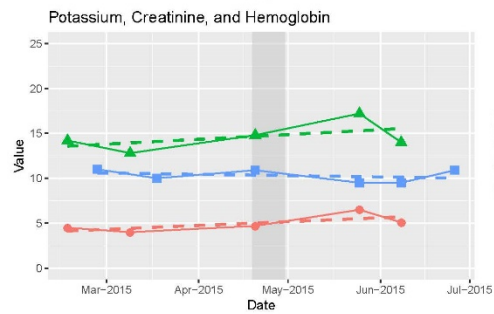
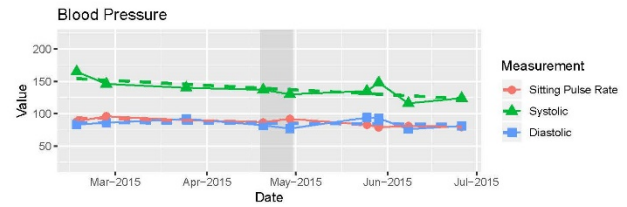
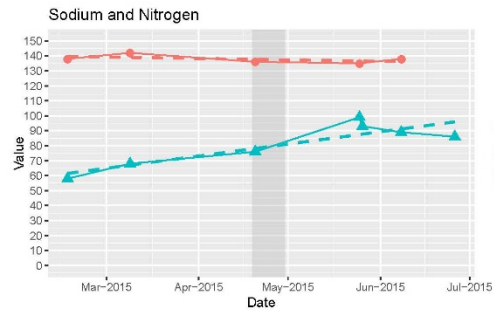
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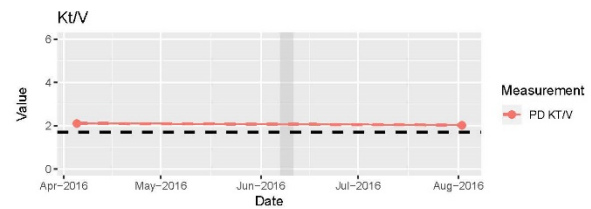
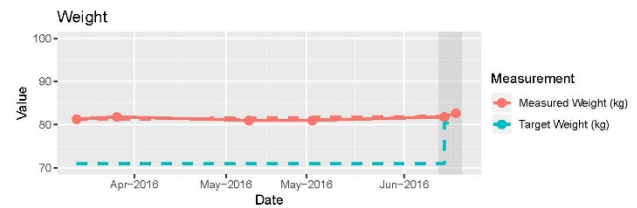
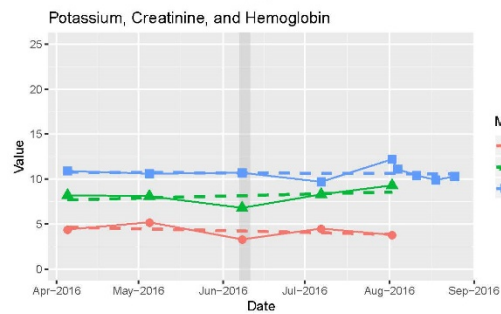
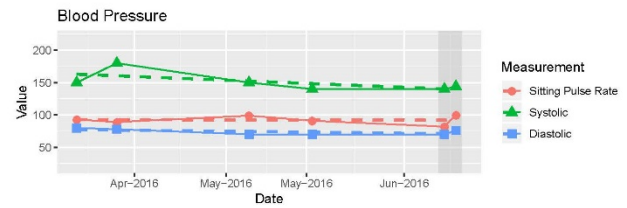
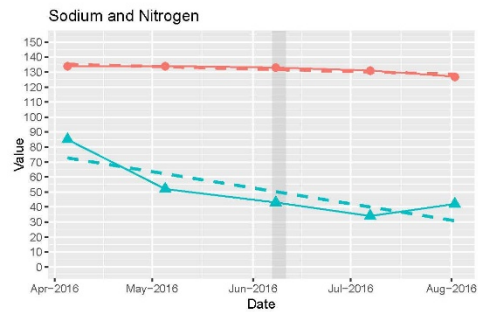
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Sample: 47



Sample: 83



Sample: 85

