

Department of Health and Human Services

**OFFICE OF  
INSPECTOR GENERAL**

**INTEGRATED HEALTH  
ADMINISTRATIVE SERVICES, INC.,  
IMPROPERLY CLAIMED MEDICARE  
PART B REIMBURSEMENT FOR  
PORTABLE X-RAY SERVICES**

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# *Office of Inspector General*

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## EXECUTIVE SUMMARY

***Integrated Health Administrative Services, Inc., improperly claimed at least \$914,000 Medicare Part B reimbursement for portable x-ray services provided during the period January 1, 2012, through June 30, 2014.***

### WHY WE DID THIS REVIEW

Medicare Part B allows approved portable x-ray providers to claim reimbursement for portable x-ray services provided to a Medicare beneficiary in their place of residence. Prior Office of Inspector General (OIG) reviews identified questionable billing patterns by portable x-ray providers, including billing for services ordered by non-physicians and services that were not medically necessary or adequately documented. We reviewed claims for portable x-ray services submitted for Medicare reimbursement by Integrated Health Administrative Services, Inc., (Integrated) because it ranked among the highest-paid providers of portable x-ray services in New York and New Jersey.

The objective of this review was to determine whether portable x-ray services provided by Integrated complied with Medicare requirements.

### BACKGROUND

Portable x-ray services covered by Medicare include skeletal films of arms, legs, pelvis, spine, skull, chest, and abdomen, as well as electrocardiograms and mammograms. Medicare Part B pays for all services related to the portable x-ray, including transporting the x-ray equipment to the beneficiary's place of residence, preparing the x-ray equipment, performing the x-ray, and interpreting the results of the x-ray. The Centers for Medicare & Medicaid Services (CMS), which administers the Medicare program, contracts with Medicare Administrative Contractors (MACs) to process and pay Part B claims.

To be covered by Medicare, portable x-ray services must be medically necessary and ordered by a physician or qualified practitioner. The order must specify the reason why the x-ray is required, the area of the body to be exposed, the number of x-rays to be taken, the views needed, and why portable x-ray services are necessary. Additionally, portable x-ray providers must maintain a record for each patient that includes at a minimum, the written and signed order, the date and a description of the x-ray taken, the technician performing the x-ray, and the date and physician to whom the x-ray was sent for interpretation. Finally, Medicare allows for a single transportation payment for each trip a supplier makes to a particular location. When more than one Medicare patient is x-rayed at the same location, the payment is prorated among all beneficiaries that received services.

Under section 1128J(d) of the Social Security Act and 42 CFR part 401 subpart D (the 60-day rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (42 CFR § 401.305(a)(2), (f) and 81 Fed. Reg.

7654, 7663) (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

## **HOW WE CONDUCTED THIS REVIEW**

Our review covered 116,548 claims for which Integrated received Medicare reimbursement totaling \$9,892,983 for portable x-ray services provided during the period January 1, 2012, through June 30, 2014 (audit period). A claim consisted of all payments made to Integrated for portable x-ray services provided to a beneficiary on the same date of service. We reviewed a stratified random sample of 112 claims.

## **WHAT WE FOUND**

Integrated improperly claimed Medicare Part B reimbursement for portable x-ray services that did not comply with certain Medicare requirements. Of the 112 claims in our sample, 91 claims complied with Medicare requirements. However, 21 did not comply with certain Medicare requirements. Specifically:

- For 11 claims, services were not ordered in accordance with Medicare requirements.
- For eight claims, the documentation did not adequately support services billed.
- For four claims, transportation costs were not properly prorated.

Of the 21 claims that did not comply with Medicare requirements, 2 contained more than 1 deficiency.

These improper payments occurred because Integrated did not have adequate procedures in place to ensure services were ordered by qualified practitioners or that transportation costs were billed correctly. Integrated also did not maintain documentation that adequately supported the services for which it claimed Medicare reimbursement.

On the basis of our sample results, we estimated that Integrated improperly received at least \$914,109 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period. This unallowable amount includes claims outside the 4-year claim-reopening period.

## **WHAT WE RECOMMEND**

We recommend that Integrated:

- refund to the Federal Government the portion of the estimated \$914,109 for portable x-ray services that did not comply with Medicare requirements and are within the 4-year claim-reopening period;

- for the remaining portion of the estimated \$914,109, which is outside of the Medicare reopening period, exercise reasonable diligence to investigate the potential overpayments and work with the MAC to return any identified overpayments in accordance with the 60-day repayment rule;
- 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; and
- strengthen its procedures to ensure that it complies with Medicare requirements related to portable x-ray services.

### **INTEGRATED HEALTH ADMINISTRATIVE SERVICES, INC., COMMENTS AND OUR RESPONSE**

In written comments on our draft report, Integrated, through its attorneys, generally disagreed with our findings and recommendations. Specifically, Integrated stated that nearly all of its claims for portable x-ray services complied with Medicare payment rules. Of the 24 claims questioned in our draft report, Integrated agreed that 2 did not comply with Medicare requirements for prorating transportation costs. Integrated disagreed with our determinations for the remaining 22 claims and provided detailed explanations, as well as additional documentation, related to why they believe these claims complied with Medicare requirements.

Integrated also challenged the validity of our sampling methodology and stated that the number of claims that it agreed were in error does not support our estimating the amount of Medicare improper payments made to Integrated during our audit period. Integrated stated that it would repay the two claims that it agreed were in error but does not believe it has any repayment obligation for the remaining claims.

After reviewing Integrated's comments and additional documentation, we revised our determinations for three claims that were questioned in our draft report because the services were not ordered in accordance with Medicare requirements and have revised our report and recommendations accordingly. We disagree with Integrated's contention that our sampling methodology was invalid and that the number of claims in error does not support estimating the amount of Medicare improper payments made to Integrated during our audit period. CMS will make the final determination as to the total amount to be refunded and will work with Integrated to determine whether it may have liability under the 60-day repayment rule.

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## INTRODUCTION

### WHY WE DID THIS REVIEW

Medicare Part B allows approved portable x-ray providers to claim reimbursement for portable x-ray services provided to a Medicare beneficiary in their place of residence. Prior Office of Inspector General reviews identified questionable billing patterns by portable x-ray providers, including billing for services ordered by non-physicians and services that were not medically necessary or adequately documented. We reviewed claims for portable x-ray services submitted for Medicare reimbursement by Integrated Health Administrative Services, Inc., (Integrated) because it ranked among the highest-paid providers of portable x-ray services in New York and New Jersey. (See Appendix A for related OIG reports on Medicare claims for portable x-ray services.)

### OBJECTIVE

Our objective was to determine whether portable x-ray services provided by Integrated complied with Medicare requirements.

### BACKGROUND

#### Medicare Program

Title XVIII of the Social Security Act (the Act) established the Medicare program, which provides health insurance coverage for people aged 65 and over, people with disabilities, and people with end stage renal disease. 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 portable x-ray services. CMS contracts with Medicare Administrative Contractors (MACs) to process and pay Medicare Part B claims.

#### Medicare Portable X-ray Services

Portable x-ray services covered by Medicare<sup>1</sup> include skeletal films of the arms, legs, pelvis, spine, skull, chest, and abdomen, as well as electrocardiograms (EKGs) and mammograms.<sup>2</sup> Medicare Part B pays for all services related to the portable x-ray, including transporting the x-ray equipment to the beneficiary's place of residence, preparing the x-ray equipment, performing the x-ray, and interpreting the results of the x-ray.<sup>3</sup>

To be covered by Medicare, portable x-ray services must be medically necessary and ordered by a physician or qualified practitioner.<sup>4</sup> The order must specify the reason why

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<sup>1</sup> Section 1861(s)(3) of the Act.

<sup>2</sup> 42 CFR § 410.32(c)(3) and *Medicare Benefit Policy Manual*, chapter 15, § 80.4.3.

<sup>3</sup> *Medicare Claims Processing Manual*, chapter 13 § 90.

<sup>4</sup> Section 1862(a)(1)(A) of the Act and 42 CFR § 486.106(a).

the x-ray is required, the area of the body to be exposed, the number of x-rays to be taken, the views needed, and why portable x-ray services are necessary.<sup>5</sup> Additionally, portable x-ray providers must maintain a record for each patient that includes at a minimum, the written and signed order, the date and a description of the x-ray taken, the technician performing the x-ray, and the date and physician to whom the x-ray was sent for interpretation.<sup>6</sup> Finally, Medicare allows for a single transportation payment for each trip a supplier makes to a particular location. However, when more than one Medicare patient is x-rayed at the same location, the payment is prorated among all beneficiaries that received services.<sup>7</sup>

### **Integrated Health Administrative Services, Inc.**

Integrated, located in Mamaroneck, New York, provides portable x-ray services to approximately 200 nursing homes throughout parts of New York, New Jersey, and Connecticut. During the period January 1, 2012, through June 30, 2014, Integrated employed 76 technicians. National Government Services, Inc., (NGS) and Novitas Solutions, Inc., (Novitas) serve as the MACs for Integrated's service area.<sup>8</sup>

### **HOW WE CONDUCTED THIS REVIEW**

Our review covered 116,548 claims for which Integrated received Medicare reimbursement totaling \$9,892,983 for portable x-ray services provided during the period January 1, 2012, through June 30, 2014 (audit period). A claim consisted of all payments made to Integrated for portable x-ray services provided to a beneficiary on the same date of service. We reviewed a stratified random sample of 112 claims.

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

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<sup>5</sup> 42 CFR § 486.106(a)(2).

<sup>6</sup> 42 CFR § 486.106(b).

<sup>7</sup> *Medicare Claims Processing Manual*, chapter 13, § 90.3.

<sup>8</sup> NGS serves as the MAC for services provided to beneficiaries residing in long-term care facilities in New York and Connecticut, and Novitas serves as the MAC for services provided to beneficiaries in New Jersey.

## FINDINGS

Integrated improperly claimed Medicare Part B reimbursement for portable x-ray services that did not comply with certain Medicare requirements. Of the 112 claims in our sample, 91 claims complied with Medicare requirements. However, 21 did not comply with certain Medicare requirements. Specifically:

- For 11 claims, services were not ordered in accordance with Medicare requirements.
- For eight claims, the documentation did not adequately support services billed.
- For four claims, transportation costs were not properly prorated.

Of the 21 claims that did not comply with Medicare requirements, 2 claims contained more than 1 deficiency.

These improper payments occurred because Integrated did not have adequate procedures in place to ensure services were ordered by qualified practitioners or that transportation costs were billed correctly. Integrated also did not maintain documentation that adequately supported the services for which it claimed Medicare reimbursement.

On the basis of our sample results, we estimated that Integrated improperly received at least \$914,109 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period.<sup>9, 10</sup> This unallowable amount includes claims outside the 4-year claim-reopening period.<sup>11</sup>

### **SERVICES NOT ORDERED IN ACCORDANCE WITH MEDICARE REQUIREMENTS**

Portable x-ray services must be ordered by a physician or qualified practitioner and the order must be written and signed by the ordering practitioner. During our audit period, effective January 1, 2013, Federal regulations included non-physician practitioners among the individuals

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<sup>9</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 will be less than the actual overpayment total at least 95-percent of the time.

<sup>10</sup> Under section 1128J(d) of the Act and 42 CFR part 401 subpart D (the 60-day repayment rule), upon receiving credible information of a potential overpayment, providers must: (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify the overpayment amount over a 6-year lookback period, and (3) report and return any overpayments within 60 days of identifying those overpayments (§ 42 CFR 401.305(a)(2), (f) and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016)). OIG believes that this audit report constitutes credible information of potential overpayments.

<sup>11</sup> 42 CFR § 405.980(b).

who could order portable x-ray services.<sup>12, 13</sup> The ordering practitioner must be enrolled in the Medicare program.<sup>14</sup>

The order for the portable x-ray service must specify the area of the body to be exposed, the number of x-rays to be taken, the views needed, the reason a portable x-ray is required, and a statement concerning the condition of the patient that indicates why portable x-ray services are necessary. Portable x-ray providers must maintain a record for each patient that includes at a minimum, the written and signed order by an authorized practitioner.<sup>15</sup>

For 11 claims, Integrated claimed Medicare reimbursement for portable x-ray services that were not ordered in accordance with Medicare requirements. Specifically:

- For 9 claims, the portable x-ray services were not ordered by a physician or qualified practitioner. This included 8 claims where the order was not signed by a physician or non-physician practitioner and 1 claim where the services were ordered by a nurse practitioner who was not enrolled in Medicare.
- For two claims, Integrated did not provide a physician order for some of the services on these claims.

## **SERVICES NOT SUPPORTED**

Payments to Medicare providers should not be made unless the provider has furnished information necessary to determine the amount due the provider.<sup>16</sup> The order for the portable x-ray service must specify the area of the body to be exposed, the number of x-rays to be taken, the views needed.<sup>17</sup>

For eight claims, the documentation Integrated provided did not support the services claimed. This included seven claims for which the number of x-ray views provided was greater than the number of views ordered<sup>18</sup> and one claim for which the services claimed were different from those ordered and performed.<sup>19</sup>

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<sup>12</sup> 42 CFR § 486.106(a).

<sup>13</sup> Non-physician practitioners include licensed nurse practitioners and physician assistants.

<sup>14</sup> 42 CFR § 424.507(a)(2)(i).

<sup>15</sup> 42 CFR § 486.106(a)(2) and (b).

<sup>16</sup> Section 1833(e) of the Act.

<sup>17</sup> 42 CFR § 486.106(a)(2).

<sup>18</sup> For these seven claims, the order did not specify the number of views to be taken, as required. As such, we allowed the minimum number of views.

<sup>19</sup> For these services, we questioned the difference in Medicare reimbursement between what was claimed and what was eligible for reimbursement.

## **TRANSPORTATION COSTS NOT PROPERLY PRORATED**

Medicare reimburses portable x-ray providers for transporting the x-ray equipment to beneficiaries. Medicare allows for a single transportation payment for each trip a supplier makes to a particular location (e.g., a nursing home). When more than one Medicare patient is x-rayed at the same location, the payment is prorated among all Medicare beneficiaries that received services.<sup>20</sup>

For four claims, Integrated did not prorate transportation costs in accordance with Medicare requirements.<sup>21</sup> For example, for one claim, Integrated claimed Medicare reimbursement for the transportation of equipment for a single beneficiary; however, Integrated's documentation indicated that two Medicare beneficiaries received services during the same trip; therefore, transportation costs should have been prorated among two beneficiaries.

## **CONCLUSION**

On the basis of our sample results, we estimated that Integrated improperly received at least \$914,109 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period. This unallowable amount includes claims outside of the 4-year claim-reopening period.

## **RECOMMENDATIONS**

We recommend that Integrated:

- refund to the Federal Government the portion of the estimated \$914,109 for portable x-ray services that did not comply with Medicare requirements and are within the 4-year claim-reopening period;
- for the remaining portion of the estimated \$914,109, which is outside of the Medicare reopening period, exercise reasonable diligence to investigate the potential overpayments and work with the MAC to return any identified overpayments in accordance with the 60-day repayment rule;
- 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; and
- strengthen its procedures to ensure that it complies with Medicare requirements related to portable x-ray services.

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<sup>20</sup> *Medicare Claims Processing Manual*, chapter 13, § 90.3.

<sup>21</sup> For these services, we questioned the difference in Medicare reimbursement between what was claimed and what was eligible for reimbursement.

## **OTHER MATTER: REASON FOR REQUESTING PORTABLE X-RAY SERVICES WAS NOT BENEFICIARY-SPECIFIC**

Medicare regulations require that all portable x-ray services be ordered by a physician or qualified practitioner and that the order include a statement concerning the condition of the patient that indicates why portable x-ray services are necessary.<sup>22</sup>

For the 112 sample claims, Integrated received orders for portable x-ray services electronically or manually, via hard copy. Both types of orders contained a reason for the x-ray and/or the patient's active diagnoses. The manual orders also contained the following preprinted statement: "A portable x-ray is being ordered since this patient would find it physically and/or psychologically taxing because of advanced age and/or physical limitations to receive x-ray outside the home. This test is medically necessary for the diagnosis and treatment of this patient." For all sample claims, there was no other patient-specific information on the orders or other documents maintained by Integrated indicating why portable services were necessary.

According to CMS officials, the intent of the Medicare requirement that the need for portable services be documented was to have a patient-specific reason that would justify the more costly portable x-ray services. We believe the information included in Integrated's records is too general to meet Medicare's requirement. Therefore, to document the need for the x-ray, additional patient-specific information is needed in the patient's records. However, the Medicare requirement is not clear as to how portable x-ray providers are to document the need for the service. Therefore, we are not questioning sample claims for this reason.

## **INTEGRATED HEALTH ADMINISTRATIVE SERVICES, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE**

In written comments on our draft report, Integrated, through its attorneys, generally disagreed with our findings and recommendations. Specifically, Integrated stated that nearly all of its claims for portable x-ray services complied with Medicare payment rules. Of the 24 claims questioned in our draft report, Integrated agreed that 2 did not comply with Medicare requirements for prorating transportation costs. Integrated disagreed with our determinations for the remaining 22 claims and provided detailed explanations, as well as additional documentation, related to why they believe these claims complied with Medicare requirements.<sup>23</sup>

Integrated also challenged the validity of our sampling methodology and stated that the number of claims that it agreed were in error does not support our estimating the amount of Medicare improper payments made to Integrated during our audit period. Integrated stated that it would repay the two claims that it agreed were in error, totaling \$90, but does not believe it has any repayment obligation for the remaining claims. Integrated's comments are included as Appendix E.

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<sup>22</sup> 42 CFR § 486.106(a)(2).

<sup>23</sup> We did not include exhibits submitted as attachments to Integrated's comments because they were voluminous. Further, some exhibits contained personally identifiable information.

After reviewing Integrated's comments and additional documentation, we revised our determinations for three claims that were questioned in our draft report because the services were not ordered in accordance with Medicare requirements and have revised our report and recommendations accordingly. We disagree with Integrated's contention that our sampling methodology was invalid and that the number of claims in error does not support estimating the amount of Medicare improper payments made to Integrated during our audit period.

## **SERVICES NOT ORDERED IN ACCORDANCE WITH MEDICARE REQUIREMENTS**

### **Integrated Comments**

Integrated stated that Medicare rules do not require a signature on an order or referral for portable x-ray services. Further, Integrated stated that we relied on an "outdated regulation" at 42 CFR § 486.106(a)(2) in determining whether orders met Medicare requirements. According to Integrated, Federal regulations (42 CFR § 410.32) do not require orders for portable x-ray services to include a practitioner signature and that such a requirement was eliminated from CMS policy guidance "many years ago." Integrated cited chapter 15, § 80.6.1 of the *Medicare Benefit Policy Manual*, which states that, as of 2003, no signature is required on orders for clinical diagnostic tests paid on the basis of the physician fee schedule. Therefore, according to Integrated, such orders do not require a physician's or non-physician practitioner's signature.

Regarding the two claims for which we determined that services were ordered by a nurse practitioner who was not enrolled in Medicare, Integrated stated that the nurse practitioner only signed for the orders for these services to acknowledge that a Medicare-enrolled physician had placed them. According to Integrated, these services were essentially denied because the orders were not signed by the referring physician, which is not required.

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

Based on our review of Integrated's comments and additional documentation, we are no longer questioning 3 of the 14 claims questioned in our draft report because services were not ordered in accordance with Medicare requirements.<sup>24</sup> However, we maintain that portable x-ray services for the remaining 11 claims were not ordered in accordance with Medicare requirements.

Federal regulations (42 CFR § 486.106) require portable x-ray services to be ordered by a qualified practitioner, and that the order be written and signed by the ordering practitioner. The regulation that Integrated cited (42 CFR § 410.32) is not applicable to portable x-ray services. Specifically, 42 CFR § 410.32(a) explicitly exempts portable x-ray services from the general ordering rules for diagnostic tests and cites regulations found at 42 CFR § 486.106 as the

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<sup>24</sup> This includes two claims where the order was not signed by a physician or non-physician practitioner and one claim where the services were ordered by a nurse practitioner who was not enrolled in Medicare. For these three claims, Integrated either provided additional documentation or information that it had obtained from the nursing facility where the services were provided subsequent to the issuance of our draft report.

controlling requirements for portable x-ray services.<sup>25</sup> Accordingly, we maintain that services for eight claims were not ordered in accordance with Medicare requirements because the order for portable x-ray services was not signed by the ordering physician or non-physician practitioner. For two other claims, the order did not meet Medicare requirements because it did not contain some of the services that Integrated claimed for Medicare reimbursement. Finally, we note that services on one other claim were not unallowable because the order was not signed by the referring physician, as Integrated contends. Rather, we questioned the claim because the services were ordered by a nurse practitioner who was not enrolled in the Medicare program. Integrated provided no evidence that the services related to the order were placed by a Medicare-enrolled practitioner.

## **SERVICES NOT SUPPORTED**

### **Integrated Comments**

Integrated stated that CMS guidance (chapter 15, § 80.6.4 of the *Medicare Benefit Policy Manual*) allows a Medicare provider that furnishes diagnostic tests the discretion to select the test design, including the number of views when the referring physician provides a non-specific order. Integrated contends that it had the discretion to choose the number of views when the order did not specify a number and that it could choose the test design when what was ordered could not be completed because of the patient's clinical condition. Accordingly, Integrated contends that all eight claims questioned because documentation did not support the services claimed complied with Medicare payment requirements.

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

As we describe above, Federal regulations (42 CFR § 486.106) require portable x-ray services to be ordered by a physician or qualified practitioner and that the order specify the reason why the x-ray is required, the area of the body to be exposed, the number of x-rays to be taken, the views needed, and why portable x-ray services are necessary. Integrated did not meet this requirement for the eight claims for which documentation did not support the services. Rather, the orders for these services did not specify the x-ray to be provided, the number of x-rays to be taken, or the number of views needed.

## **TRANSPORTATION COSTS NOT PROPERLY PRORATED**

### **Integrated Comments**

Integrated agreed that transportation costs for two of the four claims questioned in our draft report were not properly prorated. For the other two claims, Integrated contends that CMS guidance on prorating transportation costs is unclear. Specifically, Integrated stated that while CMS guidance (*Medicare Claims Processing Manual*, chapter 13, § 90.3) requires transportation costs to be prorated among all patients receiving services during the same trip, portable x-ray suppliers and MACs have interpreted this to mean costs should be prorated among Medicare

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<sup>25</sup> See preamble language at 77 Fed. Reg. 68892, 69011 (Nov. 16, 2012).

beneficiaries receiving Part B services only. According to Integrated, MACs in some jurisdictions have allowed transportation costs to be allocated only among Medicare Part B beneficiaries. Based on the lack of clarity in CMS guidance, Integrated believes it should be found to be without fault with regard to how it submitted claims for transportation costs.

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

We maintain that, for four claims, Integrated did not prorate transportation costs in accordance with Medicare requirements. We based our determinations on clear CMS guidance—not on an interpretation of that guidance. Accordingly, we determined whether Integrated allocated transportation costs among all Medicare beneficiaries that received portable x-ray services during the same trip. We also note that, for the four claims, the beneficiaries identified as receiving services and for whom we prorated the transportation payment, were all Medicare Part B beneficiaries.

## **VALIDITY OF SAMPLING DESIGN**

### **Integrated Comments**

Integrated stated that, per CMS guidance (*Medicare Program Integrity Manual*, chapter 8, § 8.4.1.5), we are required to have our sampling methodology reviewed by a statistician and, based on the documents we provided, this did not occur. In addition, Integrated stated that it could not replicate our sample because we did not provide the seed value or provide documentation of the sorting done on our claims data prior to assigning sample numbers, as required.<sup>26</sup> Integrated also contended that our sample included invalid health insurance claim (HIC) numbers that started with a “{” (bracket). Finally, Integrated stated that our sample design was invalid because the population included claims for two MACs and, therefore, did not account for the variations within each MAC and for each MAC’s overpayments. For these reasons, Integrated challenged the validity of the OIG’s sampling methodology.

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

We maintain that our sampling methodology was valid. Although the CMS guidance Integrated cited applies to MACs—not OIG—our sampling methodology, as detailed in Appendix B and included in the draft report, was approved by a statistician. That approval is maintained in our working papers and can be provided to Integrated once the final report is issued. In response to Integrated’s comments, we provided Integrated with the seed value and sorting information needed to replicate the sample. Regarding HIC numbers that start with a bracket, we note that these are associated with Medicare Part B Railroad Retirement Board members and are therefore valid. Finally, including claims paid by two MACs in the population does not invalidate the sample design. 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. We audited Integrated’s claims and determined that Integrated improperly claimed Medicare Part B reimbursement for portable x-ray

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<sup>26</sup> *Medicare Program Integrity Manual*, chapter 8, § 8.4.4.2.

services that did not comply with certain Medicare requirements. Given these results, we estimated the total amount incorrectly paid to Integrated using the lower limit of a two-sided 90-percent confidence interval. Lower limits calculated in this manner will be less than the actual amount incorrectly paid 95 percent of the time. This conservative approach accounts for variations resulting from differences between MACs.

## **USE OF EXTRAPOLATION**

### **Integrated Comments**

Integrated stated that, based on its opinion that only two of our sample claims were improper, such an error rate does not support our estimating overpayments (i.e., extrapolating overpayments to the total universe of claims). Integrated cited section 935 of the Medicare Modernization Act, which states that extrapolation to determine an overpayment may only be used when there is a sustained or high level of payment error or when documented educational intervention failed to correct the payment error. According to Integrated, extrapolation would only be lawful if our review demonstrated a sustained or high level of payment error.

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

We disagree with Integrated's contention that the number of claims in error does not support extrapolation. The section of the Medicare Modernization Act that Integrated cited in its comments applies to MACs—not the OIG. In addition, Federal courts have consistently upheld statistical sampling and estimation as valid means to determine overpayment amounts in Medicare.<sup>27</sup> Accordingly, we continue to stand by our determinations. CMS will make the final determinations as to the total amount to be refunded. A copy of our final report will be forwarded to the CMS action official for review and any action deemed necessary.

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<sup>27</sup> See *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).

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

<b>Report Title</b>	<b>Report Number</b>	<b>Date Issued</b>
<i>Precision Health, Inc., Improperly Claimed Medicare Part B Reimbursement for Portable X-ray Services</i>	<a href="#"><u>A-02-13-01038</u></a>	5/24/2016
<i>Questionable Billing Patterns of Portable X-Ray Suppliers</i>	<a href="#"><u>OEI-12-10-00190</u></a>	12/27/2011

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

### **SCOPE**

Our review covered 116,548 claims for which Integrated received Medicare reimbursement totaling \$9,892,983 for portable x-ray services provided during our audit period. A claim consisted of all payments made to Integrated for portable x-ray services provided to a beneficiary on the same date of service. The claims for these portable x-ray services were extracted from CMS's National Claims History file.

We did not assess Integrated's overall internal control structure. Rather, we limited our review of internal controls to those applicable to our objective. Specifically, we obtained an understanding of Integrated's policies and procedures related to portable x-ray services. Our review enabled us to establish reasonable assurance of the authenticity and accuracy of the data obtained from the National Claims History file, but we did not assess the completeness of the file.

We performed fieldwork from May 2015 through September 2016.

### **METHODOLOGY**

To accomplish our objective, we:

- reviewed applicable Medicare laws, regulations, and guidelines;
- met with CMS, NGS, and Novitas officials to gain an understanding of Medicare requirements related to portable x-ray services;
- interviewed Integrated officials to gain an understanding of Integrated's policies and procedures related to providing and claiming Medicare reimbursement for portable x-ray services;
- obtained from the CMS National Claims History file a sampling frame of 116,548 claims for portable x-ray services, totaling \$9,892,983, for portable x-ray services provided during the period January 1, 2012, through June 30, 2014, and paid during calendar years 2013 through 2014;
- selected a stratified random sample of 112 claims from the sampling frame;
- reviewed data from CMS's Common Working File and other available data for the sample claims to determine whether the claims had been canceled or adjusted;
- obtained and reviewed case records and claim payment data for each sample claim to determine whether the portable x-ray services were ordered and provided in accordance with Medicare requirements;

- estimated the total unallowable Medicare reimbursement paid in the sampling frame of 116,548 claims; and
- discussed the results of our review with Integrated 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 C: STATISTICAL SAMPLING METHODOLOGY

### POPULATION

The population consisted of all Medicare Part B portable x-ray service claims paid to Integrated for portable x-ray services provided during our audit period.

### SAMPLING FRAME

The sampling frame was an Access database containing 116,548 portable x-ray service claims, totaling \$9,892,983 paid to Integrated for services provided during our audit period. A claim consisted of all payments made to Integrated for portable x-ray services provided to a beneficiary on the same date of service. The claims data were extracted from the CMS National Claims History file.

### SAMPLE UNIT

The sample unit was a portable x-ray service claim.

### SAMPLE DESIGN

We used a stratified random sample to review Medicare Part B payments made to Integrated for portable x-ray services provided during the period January 1, 2012, through June 30, 2014, and paid during calendar years 2013 through 2014. To accomplish this, the portable x-ray service claims were separated into two strata, as follow:

<b>Stratum</b>	<b>Stratum Range</b>	<b>Number of Claims</b>	<b>Medicare Paid Amount</b>
1	Less than \$500	116,536	\$9,885,488
2	Greater than or equal to \$500	12	7,495
<b>TOTALS</b>		<b>116,548</b>	<b>\$9,892,983</b>

### SAMPLE SIZE

We selected a sample of 112 claims, as follows:

- 100 claims from stratum 1 and
- 12 claims from stratum 2.

### SOURCE OF RANDOM NUMBERS

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

## **METHOD FOR SELECTING SAMPLE ITEMS**

We consecutively numbered the portable x-ray service claims in our sampling frame. After generating 100 random numbers for stratum 1, we selected the corresponding sampling frame items. We also selected all 12 portable x-ray service claims in stratum 2.

## **ESTIMATION METHODOLOGY**

We used the OAS statistical software to calculate the total amount of Medicare overpayments paid to Integrated during our audit period at the lower limit of the 90-percent confidence interval.

**APPENDIX D: SAMPLE RESULTS AND ESTIMATES**

**Sample Details and Results**

<b>Stratum</b>	<b>Claims in Frame</b>	<b>Value of Frame</b>	<b>Sample Size</b>	<b>Value of Sample</b>	<b>Number of Unallowable Claims</b>	<b>Value of Unallowable Claims</b>
1	116,536	\$9,885,488	100	\$9,342	17	\$1,526
2	12	7,495	12	7,495	4	815
<b>Total</b>	116,548	\$9,892,983	112	\$16,837	21	\$2,341

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

Point estimate	\$1,779,364
Lower limit	\$914,109
Upper limit	\$2,644,618

APPENDIX E: INTEGRATED HEALTH ADMINISTRATIVE SERVICES, INC.,  
COMMENTS

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February 8, 2017

VIA FEDERAL EXPRESS

Marlyn Griffis, Assistant Regional IG for Audit Services  
DHHS, Office of Inspector General  
Office of Audit Services, Region II  
Jacob K. Javits Federal Building  
26 Federal Plaza, Room 3900  
New York, NY 10278

RE: Integrated Health Administrative Services, Inc.'s Response to  
DHHS, OIG Draft Audit Report No. A-02-15-01008

Dear Ms. Griffis:

The enclosed correspondence is being submitted on behalf of Integrated Health Administrative Services, Inc. ("Integrated Health") in response to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") draft report, "Integrated Health Administrative Services, Inc., Improperly Claimed Medicare Part B Reimbursement for Portable X-Ray Services" (the "Draft Report"). Our firm was engaged to assist Integrated Health in its response to the Draft Report. In accordance with our prior communication with James P. Edert, Regional Inspector General for Audit Services, this response is timely submitted by the February 9, 2017 submission deadline. We appreciate your careful consideration of the enclosed response.

By way of background, Integrated Health is enrolled in the Medicare program as a Medicare-certified portable x-ray supplier. The OIG's review consisted of a stratified random sample consisting of 112 claims from a universe of 116,548 claims for portable x-ray services provided to beneficiaries with Part B coverage during the time period of January 1, 2012, through June 30, 2014. The stratification consisted of two strata which included (i) 100 claims from a random sample for which the payment was less than \$500, and (ii) all 12 claims in the universe for which the payment was greater than or

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equal to \$500. The review identified 24 claims that allegedly did not comply with the Medicare payment requirements. The amount paid on the 24 claims was \$2,496; however, based on an extrapolation of the error rate to the universe of claims the identified overpayment amount was \$1,058,865.

Upon receipt of the Draft Report, Integrated Health, with the assistance of our firm, undertook a review of each claim line item for compliance with the Medicare payment rules for portable x-ray suppliers. This included a review of all of the associated Integrated Health patient records, which were prepared in the normal course and have been maintained on file. In addition to records that Integrated Health is required to prepare and maintain, Integrated Health obtained additional patient records from nursing facilities where the diagnostic testing occurred to support payment for the claim. The spreadsheet provided by the OIG that identified the claims that were allegedly paid in error was revised to add a column to include a "Rebuttal Comment" for each claim line item and a column "Revised Questioned Amount" to indicate Integrated Health's calculation of any alleged payment error amount. In addition to referencing patient records, the Rebuttal Comments also include references to the legal analyses provided below. Following the reformatted spreadsheet<sup>1</sup> are the corresponding documents which confirm Integrated Health's adherence to the Medicare payment rules. These documents, which are separated according to the claim sample number assigned by the OIG include, include Supporting Statements, patient records<sup>2</sup> (records which were contemporaneously created during the time period in which services were ordered, rendered and follow-up services provided); and, in certain situations, a declaration which was obtained from the referring provider and evidences the provider's medical decision-making in determining that portable x-ray testing was medically necessary. The spreadsheet, Supporting Statements, patient records and declarations are all enclosed. [Exhibit 1.] These documents and legal analyses that follow confirm that the vast majority of the claims complied with the Medicare payment rules.

**MEDICARE RULES DO NOT REQUIRE A SIGNATURE ON AN ORDER OR  
REFERRAL FOR PORTABLE X-RAY TESTS**

In the Background section of the OIG's draft Executive Summary, where the OIG provides an overview of the Medicare statutes, regulations, and CMS manual

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<sup>1</sup> Integrated Health is providing two versions of the claims spreadsheet as requested by the OIG, i.e., a paper copy that includes the beneficiary HIC number and an electronic copy on the enclosed CD that has the HIC number column removed to allow the OIG to publish the spreadsheet.

<sup>2</sup> Where a particular patient record had information on multiple patients, the record was redacted to avoid the unnecessary disclosure of unrelated Protected Health Information.

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interpretive guidance relied upon to determine whether the Medicare rules allowed coverage for the audited claims, there is an incorrect reference to the need for a "signed order."<sup>3</sup> Ten (10) claims were denied based upon the incorrect legal assertion that a denial is appropriate -- "where the order was not signed by a physician or non-physician practitioner." In particular, in the "OIG Summary of Review Results claims spreadsheet, the reviewer noted, "Physician order signed by nursing home staff - not ordering physician." Additionally, for two (2) claims, payment was denied "where the services were ordered by a nurse practitioner who was not enrolled in Medicare." For these claims, in the "OIG Summary of Review Results claims spreadsheet, the reviewer noted, "Services Ordered by Nurse Practitioner Who Was Not Enrolled in Medicare at the time services were ordered." The reviewer then cited to the regulations at 42 C.F.R. § 424.507(a)(2)(i), which contain requirements related to the Medicare enrollment status of the physician or nonphysician practitioner who orders certain tests and services. The order, however, was provided by a Medicare-enrolled physician as required under 42 C.F.R. § 424.507(a)(2)(i). A nurse practitioner, who was additionally providing medical services to the beneficiary at issue, signed the order acknowledging that the order had been placed by the noted physician. Therefore, these two claims were denied for essentially the same reason as the other ten claims, *i.e.*, that the order was not signed by the referring physician. The OIG Draft Report and reviewer statements, which rely upon outdated regulations at 42 C.F.R. § 486.106(a)(2), fail to consider the controlling law that defines an appropriate "order" for purposes of coverage and payment for diagnostic tests, including tests performed by portable x-ray suppliers, as tests which do not require a signature by the ordering provider.

In its Draft Report, the OIG cites to the enabling statute which provides for Medicare coverage of portable x-ray diagnostic testing. Specifically, the Medicare statute defines certain covered medical and other health care services, to include:

diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary.)  
42 U.S.C. § 1395x(s)(3),<sup>4</sup>

<sup>3</sup> In the Background section of the Draft Report, footnote 6 cites to the Medicare regulations at 42 CFR § 486.106(b) as the regulation that requires a signed order for portable x-ray services. Later, in the Findings section of the Draft Report, footnote 15 additionally cites to the Medicare regulations at 42 CFR § 486.106(a)(2) as requiring a signed order. As explained below, the regulations at 42 CFR § 486.106(a)(2) are outdated and CMS simply failed to modify these outdated rules when the signature requirement for any diagnostic test paid under the physician fee schedule was removed.

<sup>4</sup> See footnote 1 in the Background section of the Draft Report referencing the corresponding Social Security Act Amendment section.

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This section of the statute does not, in any way, differentiate between portable x-rays and other diagnostic x-ray tests. Indeed, Congress has never passed a law that differentiates between portable x-rays and other diagnostic x-rays.

Certain Medicare regulations specific to portable x-ray supplier services remain unchanged since initially adopted in 1968, despite other more detailed regulations regarding conditions for payment of portable x-ray services. More recently, Medicare regulations were adopted setting forth the conditions that must be satisfied in order to receive payment for all diagnostic tests for which payment is made under the physician fee schedule. These particular regulations at 42 C.F.R. § 410.32 expressly address portable x-ray services. Most notable, the regulations at 42 C.F.R. § 410.32 were adopted under the same enabling statute supporting the adoption of the 1968 regulations cited by the OIG as providing the coverage rules for portable x-ray testing. See 33 Fed. Reg. 10149, 10150 (Jul. 16, 1968). [Exhibit 2.] Under the principles of statutory construction, it would not be an appropriate reading of the regulations as a whole to ignore the later regulations that not only address diagnostic testing generally, but contain specific provisions related to portable x-ray tests.

Following the adoption of 42 C.F.R. § 410.32 (setting forth the conditions for Medicare Part B payments for diagnostic tests) in 1997, and litigation<sup>5</sup> which is discussed more fully below, CMS amended the regulations at 42 C.F.R. § 486.106 (setting forth conditions for coverage of portable x-ray services) to expressly cite to 42 C.F.R. § 410.32 for the physician order rules for all portable x-ray services. The conditions for payment related to orders for at 42 C.F.R. § 410.32 do not include any requirement for a physician or nonphysician practitioner's signature on the order for a portable x-ray test.

In its policy guidance, many years ago CMS eliminated the requirement for the referring provider's signature on orders for portable x-ray tests. Effective for services on or after January 1, 2003, CMS no longer requires a signature on an order for a diagnostic test paid under the physician fee schedule. In general, Section 80.6 of Chapter 15 of the Medicare Benefit Policy Manual ("MBPM") sets forth CMS's guidance regarding "ordering diagnostic tests and for complying with such orders for Medicare payment." In particular, Subsection 80.6.1 expressly states, "No signature is required

<sup>5</sup> The litigation involved appeals of overpayment recoupments in which Medicare Administrative Contractors ("MACs") were applying the 1968 regulatory requirements at 42 C.F.R. § 486.106 requiring orders for portable x-ray tests to be from an M.D. or D.O. and not the later adopted regulations in 42 C.F.R. § 410.32 allowing orders from others defined as physicians under Medicare law and nonphysician practitioners.

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on orders for clinical diagnostic tests paid on the basis of . . . the physician fee schedule.”<sup>6</sup> [Exhibit 3.] Since this CMS policy was effective several years prior to the dates of service at issue in this audit, and since each clinical diagnostic test at issue is paid on the basis of the physician fee schedule, no physician’s or nonphysician practitioner’s signature is required to be included on the order or referral for any of the diagnostic tests at issue performed by Integrated Health.

Additionally, in its guidance to its contractors following the January 1, 2003 policy change with regard to orders for diagnostic tests including portable x-ray tests, CMS instructed its contractors to look for “the name of the physician who ordered the service” and be sure that this name, not a signature, is “obtained before payment may be made.” MCM, CMS Pub. 14, Part 3 § 2070.4.E.<sup>7</sup> [Exhibit 4.] Furthermore, in its guidance for processing claims for portable x-ray supply services, CMS instructs MACs to “Pay the TC of radiology services furnished by portable x-ray suppliers under the fee schedule on the same basis as TC services generally.” MCPM, CMS Pub. 100-04, Ch. 13 § 90.2. [Exhibit 5.] This particular provision confirms that CMS intends for portable x-ray services to be reviewed and approved in the same manner as a radiology test performed at a fixed location.

As noted above, there was extensive litigation following a national effort to recoup claims for 2009 dates of service for portable x-ray services that were not ordered by an M.D. or D.O. In those cases, the MACs applied the then current regulations at 42 C.F.R. § 486.106, which limited the ordering of portable x-ray tests to only an M.D. or D.O., not the later adopted regulations at 42 C.F.R. § 410.32 allowing orders from other defined physicians and nonphysician practitioners. During the course of this litigation, \* CMS revised the regulations at 42 C.F.R. § 486.06 to expand the individuals who could order a test to conform to the regulations at 42 C.F.R. § 410.32. When amending the regulations, CMS stated it was doing so because “current Medicare regulations limit the ordering of portable x-ray services to a MD or a DO.” As support for this statement, CMS cited to the OIG’s “December 2011 report entitled Questionable Billing Patterns of Portable X-Ray Suppliers (OEI-12-10-00190) [which] found that Medicare was paying for portable x-ray services ordered by physicians other than MDs and DOs, including

<sup>6</sup> The revised CMS policy guidance was initially placed in Section 15021 of the paper-based Medicare Carriers Manual (“MCM”). During the conversion to the Internet-only manuals, certain CMS policies were inadvertently not transferred from the paper-based to the Internet-only manuals. As these inadvertent omissions were discovered or brought to CMS’ attention, the policies were subsequently added to the Internet-only manuals. Transmittal 80, Change Request 5743, updated Section 80 of the Internet-only MBPM to include the requirements for physician orders for diagnostic tests formerly contained in Section 15021 of the MCM.

<sup>7</sup> During the transition to Internet-only manuals, this section was removed from the MCM by Transmittal 1821.

**\* Office of Inspector General Note:** Integrated omitted a number from the section of this citation to the CFR. The correct citation is section 486.106.

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podiatrists and chiropractors, and by nonphysician practitioners.” 77 Fed. Reg. 68892, 69009 (Nov. 16, 2012)(final regulations effective January 1, 2013) and 77 Fed. Reg. 44722, 44790 (Jul. 30, 2012)(proposed regulations).<sup>8</sup> [Exhibit 6a&b.] In rendering a legal analysis of the controlling law, administrative law judges (“ALJs”) did not agree with CMS’ statement that prior to the January 1, 2013 effective date of the revised regulations at 42 C.F.R. § 486.106, that only M.D.s and D.O.s could order covered portable x-ray tests. Rather, ALJs applying statutory construction principals, found the more recent and more frequently updated regulations at 42 C.F.R. § 410.32 to be controlling over the outdated regulation at 42 C.F.R. § 486.106. Equally important is that ALJs did not find CMS’ statement that “current Medicare regulations limit the ordering of portable x-ray services to a MD or a DO” to be persuasive. See e.g., *Appeal of Precision Health, Inc.*, DHHS, OMHA, ALJ Appeal No. 1-1517240581. [Exhibit 7.] Accordingly, the same statutory construction analysis that led to favorable determinations for the providers in this litigation would necessitate a finding that the more current and updated regulations at 42 C.F.R. § 410.32, and CMS’ implementing guidance, have removed any requirement for the referring provider to sign the order for a diagnostic test, including a portable x-ray test, paid under the physician fee schedule.

Based on the application of the controlling law, any decision to deny a claim based on the lack of the signature of the referring physician on the order should be reversed. Although Integrated Health understands that the referring physician’s or nonphysician practitioner’s signature is not required, it has nevertheless enclosed a signed order where one had been obtained from the nursing facility where services were provided and/or a declaration from the referring provider confirming that the order was placed and that it was medically necessary. Some of these additional patient records and all of the declarations were obtained after Integrated Health provided records to the OIG to review for this audit. Refer to the documents in Exhibit 1.

**MEDICARE PAYMENT RULES PROVIDE THE TESTING FACILITY  
DISCRETION TO SELECT THE TEST DESIGN**

In the Draft Report, for eight (8) claims the OIG noted the documentation that Integrated Health had submitted “did not support the services claimed.” With regard to seven (7) claims, the OIG noted the claim was submitted with a greater number of views than the records indicated had been taken. With regard to the other one (1) claim, the OIG noted a discrepancy between what was ordered and the testing

<sup>8</sup> It is worth noting that the sole focus of the proposed and final regulations was to respond to the pending litigation and the efforts by stakeholders to have CMS recognize that its prior guidance had supported coverage for portable x-ray services ordered by other physicians and nonphysician practitioners. At no time in its discussion of proposed or final regulatory changes did CMS mention or address its outdated regulation requiring a signature on an order for portable x-ray tests.

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performed. For this one order, the actual number of views ordered is what was performed. The order did request the diagnostic testing to be performed with the patient standing; however, that was not possible based on the patient's clinical condition. Although there was a payment differential for this one claim, Integrated Health was actually underpaid for that claim. For all eight claims, Integrated Health had discretion to choose the test design. Accordingly, these claims were properly submitted and should be paid.

As noted above, Section 80.6 of Chapter 15 of the MBPM sets forth CMS's guidance regarding compliance with diagnostic testing orders to receive Medicare payment. Subsection 80.6.4 expressly allows the interpreting physician of a testing facility to determine the test design, without notifying the referring physician, when the test design is not specified in the referring physician's order. In particular, Subsection 80.6.4 contains the following guidance regarding "test design":

Unless specified in the order, the interpreting physician may determine, without notifying the treating physician/practitioner, the parameters of the diagnostic test (e.g., number of radiographic views obtained, thickness of tomographic sections acquired, use or non-use of contrast media).  
MBPM, CMS Pub. 100-02, Ch. 15 § 80.6.4 (emphases added). [Exhibit 8.]

"Testing facility" is defined in Subsection 80.6.1 as "a Medicare provider or supplier that furnishes diagnostic tests." [Exhibit 3.] The guidance continues by providing examples, and not an exhaustive listing, of testing facilities. Integrated Health meets this definition as it is a "supplier that furnishes diagnostic tests."

Integrated Health's interpreting physician was allowed, under CMS's guidance, to establish a particular test design, which includes a specific number of views, when the referring physician provides a non-specific order such as "x-ray of R [right] shoulder." Integrated Health utilizes a "Radiology Requisition" that was designed and approved by its interpreting physician. [Exhibit 9.] In developing the form, the interpreting physician identified the number of views to be performed in a situation where a non-specific order is received. The identified number is based upon standards of care and routine radiological protocols. The Medicare rules were followed when the technician followed the test design developed by Integrated Health's interpreting physician. The seven claims in which Integrated Health had discrepancy to choose the specific number of views when the order did not specify the number complied with the Medicare payment rules. Integrated Health further believes the one order in which the number of views ordered were performed also complies with the rules allowing for

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discretion to complete the testing with the patient lying down when it is not possible for the patient to safely stand for the testing.

#### TRANSPORTATION COSTS NOT PROPERLY PRORATED

With respect to four (4) claims, in the Draft Report the OIG noted that Integrated Health "did not prorate transportation costs in accordance with Medicare requirements." With regard to these claims, the reviewer commented that the "documentation provided" reflected that more "Medicare patients" were seen during the trip than were identified on the claim. For two (2) claims, Integrated Health disagrees with the reviewer's findings.

For the years at issue in this audit, the guidance from CMS regarding how to bill for transportation services was interpreted by not only portable x-ray suppliers but also by MACs to require the modifier that appropriately noted the number of beneficiaries with Part B coverage who received portable x-ray services during the same trip to a particular location. CMS instructed, "When more than one Medicare patient is x-rayed at the same location, e.g., a nursing home, prorate the single fee schedule transportation payments among all patients receiving the services." MCPM, CMS Pub. 100-04, Ch. 13 § 90.3. [Exhibit 10.] This particular language, however, had been interpreted by MACs to refer only to Medicare patients receiving Part B services, perhaps because it appears in a chapter of the Medicare manual where other sections expressly identify what rules also apply to beneficiaries with Part A coverage. In fact, when CMS proposed and then finalized the 2016 Physician Fee Schedule rules, CMS decided to clarify how the transportation fee should be prorated on a going forward basis, acknowledging how the requirement had been interpreted in the past. In particular, CMS stated:

In some jurisdictions, Medicare contractors have been allowing the portable X-ray transportation fee to be allocated only among Medicare Part B beneficiaries.

...

For CY 2016, we proposed to revise the Medicare Claims Processing Manual (Pub. 100-4, Chapter 13, Section 90.3) to remove the word "Medicare" before "patient" in section 90.3. We also proposed to clarify that this subregulatory guidance means that, when more than one patient is X-rayed at the same location, the transportation payment under the PFS for the Part B patient(s) is to be prorated by allocating the trip among all patients (Medicare Parts A and B, and non-Medicare) receiving portable X-ray services during that trip, regardless of their insurance status.

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80 Fed. Reg. 70886, 71068-69 (Nov. 16, 2015)(emphasis added). [Exhibit 11.]

Even if CMS intended for the proration to be among all Medicare beneficiaries (*i.e.*, those with Part A and Part B coverage), based on the lack of clarity in its guidance and CMS's acknowledgment that its own contractors were allowing the proration to be only among Part B beneficiaries, Integrated Health should be found to be without fault with regard to how it submitted claims for these services and the claims should not be downcoded.

For two claims that were identified as not having the proper proration of the transportation services, Integrated Health agrees with the OIG's findings and will timely refund the identified payment differential amounting to \$89.54. For the reasons discussed below, the amount of the overpayment for these two isolated errors should not be used to extrapolate to the universe of claims.

#### SAMPLING DESIGN AND OVERPAYMENT CALCULATION IS ERRONEOUS

The OIG reported that it drew a statistically valid random sample (SVRS) to be audited in lieu of conducting a claim-by-claim review with respect to the claims in the stratum for which the payment was less than \$500. The OIG Draft Report included a recommendation for recoupment of the SVRS based on the extrapolated overpayment to the universe of claims.

Under CMS guidance in Section 8.4.1.5 of Chapter 8 of the Medicare Program Integrity Manual ("MPIM"), the sampling methodology "must be reviewed by a statistician," requiring that the OIG "shall obtain from the statistical expert a written approval of the methodology." [Exhibit 12.] In the documents received from the OIG, there is no written approval of the sampling methodology by a statistician.

Additionally, according to Section 8.4.4.2 of Chapter 8 of the MPIM, the OIG "shall document any starting point if using a random number table or drawing a systematic sample" and "shall document all steps taken in the random selection process exactly as done to ensure that the necessary information is available for anyone attempting to replicate the sample selection." [Exhibit 13.] In the documents received from the OIG, the seed value used in the OAS software was not recorded. There was also no documentation of specific sorting done on the data prior to assigning sample numbers. Accordingly, Integrated Health was unable to replicate the sample.

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Integrated Health notes other inconsistencies regarding the sampling methodology. These inconsistencies include:

1. There is no indication how the sample size was calculated or how the sample size was selected. This does not invalidate the sample; however, Integrated Health was provided no documentation to fully explain the process for sample selection.
2. The sample included health insurance claim "HIC" numbers that appear to be invalid. There are 191 sampling units in the sampling frame for stratum one with a HIC number that start with a "{". This is not a valid first character for a HIC number. Due to this extra character in this 191 sampling units, it is not possible to replicate the sampling frame or determine if there is a duplication of a sampling unit.
3. The universe involved claims that had been submitted to at least two different MACS (National Government Services and Novitas Solutions, Inc.), yet the sample and extrapolation were not designed to account for each of the MAC's individual repayment amounts. For that reason, the design use is not valid to account for each specific overpayment and the variation within each MAC.

For the reasons noted above, Integrated Health is challenging the validity of the sampling methodology utilized by the OIG. Even though Integrated Health believes that further review of the legal arguments and enclosed documentation will result in a diminishment of the error rate such that extrapolation will no longer be permissible, in the alternative Integrated Health urges that the inconsistencies in the sampling methodology need to be addressed and resolved prior to determining it is appropriate to extrapolate the error rate to the universe to determine an overpayment amount for the claims in stratum one.

#### ERROR RATE DOES NOT SUPPORT EXTRAPOLATION

Integrated Health respectfully urges that when the applicable payment rules are applied to the 24 claims originally determined by the OIG to not comply with the Medicare requirements, the remaining error rate of a few different types of claims will not support extrapolation to the 116,548 claims in the universe. As noted on the enclosed spreadsheet, Integrated Health agrees with the findings in the Draft Report on only a small number of claims, resulting in a less than one percent (<1%) error rate that

is simply too low to allow extrapolation. Integrated Health identified that of the total Medicare payment amounting to \$16,837.00 in the claims sample, only \$89.54 or less than one percent (<1%) was paid in error. For the remaining claims, Integrated Health has either provided its legal reasoning as to why the coverage rules were followed and/or has submitted additional documentation to support payment for the claims.

\* In 2003, Congress passed the Medicare Modernization Act (“MMA”) specifying in Section 953 that, with respect to Medicare claims, extrapolation of an error rate to the universe of claims to determine an overpayment may only be used when there is a “sustained or high level of payment error” or “documented educational intervention has failed to correct the payment error.” 42 U.S.C. § 1395ddd(f)(3). [Exhibit 14.] These two reasons were not provided as examples -- rather the legislation specified that only these two reasons would support extrapolation to determine an overpayment amount. Neither of these situations exists in the claims at issue.

CMS incorporated this MMA provision into its guidance in the MPIM, instructing that “before using extrapolation to determine overpayment amounts to be recovered by recoupment, offset or otherwise, there must be a determination of sustained or high level of payment error or documentation that educational intervention has failed to correct the payment error.” MPIM, Ch. 8 § 8.4.1.2 (emphasis added). [Exhibit 15.] Nowhere in the Draft Report has the OIG alleged that the identified payment errors are the result of a failed educational intervention. Therefore, extrapolation would only be lawful in this case if a careful and appropriate review of the 24 claims at issue demonstrates a “sustained or high level of payment error.”

Integrated Health asserts that the MMA provisions expressly note that “a Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise” unless the Secretary determines one of the above two stated reasons applies. To the extent that the OIG disagrees with Integrated Health’s response with regard to the claim determinations it is disputing, the OIG will direct the applicable MAC to issue an overpayment demand to recoup the amount the OIG determines was paid in error. Should that occur, this statute prohibits the MAC from using any extrapolated overpayment calculation which did not comply with the MMA Section 953 restrictions. Therefore, the OIG is indirectly bound by these provisions.

Integrated Health respectfully submits that when the error rate for the SVRS is re-calculated to reflect appropriate claims payment determinations based on the evidence in its response to the Draft Report, any remaining isolated payment errors for

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**\* Office of Inspector General Note:** Integrated transposed the section of this citation to the MMA. The correct citation is section 935.

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a particular claim line item will fail to rise to the "sustained or high level of payment error" required by the statute to support extrapolation.

#### REPAYMENT OBLIGATION

With respect to the limited number of claims to which Integrated Health agrees with the findings in the Draft Report, Integrated Health will promptly make repayment. With regard to the remaining claims for which Integrated Health has provided Rebuttal Comments disagreeing with the reviewer's findings, Integrated Health does not believe it has any repayment obligation since the claims complied with the conditions for payment and coverage for portable x-ray services. Accordingly, Integrated Health does not believe that those claims are subject to the 60-day repayment rule cited in footnote 10 on page three of the Draft Report.

In closing, Integrated Health wishes to thank the OIG for carefully considering its responses to the OIG's findings in its Draft Report. Integrated Health takes care to comply with the Medicare conditions for coverage and payment rules and believes that the resulting low error rate, after consideration of the legal and factual issues raised in its response, reflects its efforts to do so. Should you have any questions or wish to further discuss this response, please do not hesitate to contact us.

Sincerely,

Julie E. Kass

Donna J. Senft

Enclosures

cc: Taryn Tanzer, President

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