

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

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

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OFFICE OF AUDIT SERVICES FINDINGS AND OPINIONS

The designation of financial or management practices as questionable, a recommendation for the disallowance of costs incurred or claimed, and any other conclusions and recommendations in this report represent the findings and opinions of OAS. Authorized officials of the HHS operating divisions will make final determination on these matters.

EXECUTIVE SUMMARY

Precision Health, Inc., improperly claimed at least \$332,000 in Medicare Part B reimbursement for portable x-ray services over a 22-month period.

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 Precision Health, Inc., (Precision) 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 Precision 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, 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. The physician's 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 physician 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.

HOW WE CONDUCTED THIS REVIEW

Our review covered 97,279 claims for which Precision received Medicare reimbursement totaling \$7,829,074 for portable x-ray services provided during the period January 1, 2011, through October 31, 2012. A claim consisted of all payments made to Precision for portable x-ray services provided to a beneficiary on the same date of service. We reviewed a stratified random sample of 117 claims.

WHAT WE FOUND

Precision improperly claimed Medicare Part B reimbursement for portable x-ray services that did not comply with certain Medicare requirements. Of the 117 claims in our sample, 88 claims complied with Medicare requirements. However, 29 did not comply with certain Medicare requirements. Specifically:

- For 14 claims, services were not ordered in accordance with Medicare requirements.
- For 14 claims, the documentation did not adequately support services billed.
- For one claim, physician supervision requirements were not met.
- For one claim, transportation costs were not properly prorated.

Of the 29 claims that did not comply with Medicare requirements, 2 contained more than 1 deficiency.

These improper payments occurred because Precision did not have adequate procedures in place to ensure services were ordered by a physician, properly supervised, or that transportation costs were billed correctly. Precision 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 Precision improperly received at least \$332,233 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period. This overpayment amount includes payment dates that are outside of the 3-year recovery period. Of the total estimated overpayments, at least \$120,628 was within the 3-year recovery period, and as much as \$211,605 was outside the 3-year recovery period.

WHAT WE RECOMMEND

We recommend that Precision:

- refund \$120,628 to the Federal Government for portable x-ray services that did not comply with Medicare requirements and that are within the 3-year claims recovery period;
- work with the MACs to return overpayments outside of the 3-year recovery period, which we estimate to be as much as \$211,605 for our audit period, in accordance with the 60-day repayment rule; and
- strengthen its procedures to ensure that it complies with Medicare requirements related to portable x-ray services.

PRECISION HEALTH, INC., COMMENTS AND OUR RESPONSE

In written comments on our draft report, Precision, through its attorneys, partially agreed with our recommendations. Specifically, Precision stated that most of its claims for portable x-ray services complied with Medicare payment rules. Of the 59 claims questioned in our draft report, Precision agreed that 8 did not comply with Medicare requirements. However, it disagreed—either fully or in part—with our determinations for the remaining 51 claims and provided detailed explanations as to why these claims complied with Medicare requirements, as well as additional documentation for other claims.

Precision also 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 Precision during our audit period. Finally, Precision stated that it would repay the eight claims that it agreed were in error. However, Precision does not believe it has any repayment obligation for the remaining claims because those claims complied with Medicare coverage conditions for portable x-ray services and therefore, are not subject to the 60-day repayment rule.

After reviewing Precision's comments and additional documentation, we revised our determinations for 37 claims. Specifically, we are no longer questioning 25 claims for which services were not ordered in accordance with Medicare requirements, 8 claims for which the performing technician was not identifiable, 7 claims for which physician supervision requirements were not met, and 7 claims that contained services provided by unqualified technicians. The total exceeds 37 because 9 of the claims had more than 1 deficiency that we are no longer questioning. We revised our report and recommendations accordingly; however, for 7 of the 37 claims for which we revised our determinations, the claims remain unallowable for other reasons. Finally, we disagree with Precision's contention that the number of claims in error does not support extrapolation. CMS will make the final determination as to the total amount to be refunded and will work with Precision 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 (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 Precision Health, Inc., (Precision) because it ranked among the highest-paid providers of portable x-ray services in New York and New Jersey.

OBJECTIVE

Our objective was to determine whether portable x-ray services provided Precision 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 Medicare¹ include skeletal films of the arms, legs, pelvis, spine, skull, chest, and abdomen, as well as electrocardiograms (EKGs) and mammograms.² 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.³

To be covered by Medicare, portable x-ray services must be medically necessary and ordered by a physician.⁴ The physician's 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

¹ Section 1861(s)(3) of the Act.

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

³ *Medicare Claims Processing Manual*, chapter 13 § 90.

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

needed, and why portable x-ray services are necessary.⁵ Additionally, portable x-ray providers must maintain a record for each patient that includes at a minimum, the written and signed physician 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.⁶

Precision Health, Inc.

Precision, located in Staten Island, New York, provides portable x-ray services to 160 nursing homes throughout parts of New York, New Jersey, and Connecticut. During the period January 1, 2011, through October 31, 2012 (audit period), Precision employed 75 technicians, including 51 radiologist technicians, 16 ultrasound technicians, and 8 EKG technicians. National Government Services, Inc., (NGS) and Novitas Solutions, Inc., (Novitas) serve as the MACs for Precision's service area.⁷

HOW WE CONDUCTED THIS REVIEW

Our review covered 97,279 claims for which Precision received Medicare reimbursement totaling \$7,829,074 for portable x-ray services provided during our audit period. A claim consisted of all payments made to Precision for portable x-ray services provided to a beneficiary on the same date of service. We reviewed a stratified random sample of 117 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 A contains details of our audit scope and methodology, Appendix B contains our statistical sampling methodology, and Appendix C contains our sample results and estimates.

FINDINGS

Precision improperly claimed Medicare Part B reimbursement for portable x-ray services that did not comply with certain Medicare requirements. Of the 117 claims in our sample, 88 claims complied with Medicare requirements. However, 29 did not comply with certain Medicare requirements. Specifically:

- For 14 claims, services were not ordered in accordance with Medicare requirements.

⁵ 42 CFR § 486.106(a)(2).

⁶ 42 CFR § 486.106(b).

⁷ 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.

- For 14 claims, the documentation did not adequately support services billed.
- For one claim, physician supervision requirements were not met.
- For one claim, transportation costs were not properly prorated.

Of the 29 claims that did not comply with Medicare requirements, 2 contained more than 1 deficiency.

These improper payments occurred because Precision did not have adequate procedures in place to ensure services were ordered by a physician, properly supervised, or that transportation costs were billed correctly. Precision 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 Precision improperly received at least \$332,233 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period. This overpayment amount includes payment dates that are outside the 3-year recovery period. Of the total estimated overpayments, at least \$120,628 was within the 3-year recovery period, and as much as \$211,605 was outside the 3-year recovery period.^{8,9}

SERVICES NOT ORDERED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Portable x-ray services must be ordered by a licensed doctor of medicine or doctor of osteopathy, and the order must be written and signed by the ordering physician. In addition, the order must specify the area of the body to be exposed, the number of x-rays to be taken, the views needed, and why the portable x-ray services are necessary. Furthermore, portable x-ray providers must maintain a record for each patient that includes at a minimum, the written and signed physician order.¹⁰

For 14 claims, Precision claimed Medicare reimbursement for portable x-ray services that were not ordered in accordance with Medicare requirements. Specifically:

⁸ Our audit report represents the results for all claims within our audit period. Section 1870(b) of the Act governs the recovery of excess payments. This section provides that excess payments identified are barred from recovery three years after the year in which the original payment was made. In addition, Precision is responsible for reporting and returning overpayments they identified to the MACs. The 2010 Patient Protection and Affordable Care Act requires the reporting and return of Medicare overpayments along with written notice of the reason for the overpayment within 60-days after the overpayment was identified (60-day repayment rule). Failure to meet this deadline subjects providers to potential False Claims Act and Civil Monetary Penalty Law liability.

⁹ 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.

¹⁰ 42 CFR § 486.106(a)(1), (2) and (b). This section was revised, effective January 1, 2013, to allow nonphysician practitioners to order portable x-ray services and sign such order.

- For 10 claims, the physician's order for portable x-ray services was not signed by a physician or nonphysician practitioner.
- For four claims, Precision 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.¹¹

For 14 claims, Precision claimed Medicare reimbursement for portable x-ray services that were not adequately supported.¹² Specifically:

- For 12 claims, the documentation Precision provided did not support the services claimed. This included 10 claims for which the number of x-ray views claimed was greater than the number of views taken and 2 claims for which the services claimed were different from those ordered and performed.¹³
- For three claims,¹⁴ Precision did not provide any documentation to support some of the portable x-rays services claimed for Medicare reimbursement.

PHYSICIAN SUPERVISION REQUIREMENTS NOT MET

Portable x-ray services must be performed under the supervision of a licensed physician who is qualified by advanced training and experience in the use of x-rays for diagnostic purposes.¹⁵ On an annual basis, the supervising physician certifies that the portable x-ray supplier's procedure manuals have been checked, that operators' performances have been observed, that the equipment and personnel meet applicable Federal, State, and local licensure and registration requirements, and that safe operating procedures are used.¹⁶

For one claim, Precision claimed Medicare reimbursement for services for which physician supervision requirements were not met. Specifically, these services were provided in a nursing

¹¹ Section 1833(e) of the Act.

¹² The total exceeds 14 because 1 claim contained more than one deficiency.

¹³ For these services, we questioned the difference in Medicare reimbursement between what was claimed and what was eligible for reimbursement.

¹⁴ This included one claim for which the documentation Precision provided to support the sample services was for a different beneficiary. For this claim, Precision stated that it billed Medicare for the wrong beneficiary.

¹⁵ 42 CFR § 486.102(b).

¹⁶ 42 CFR § 486.102(a)(2).

home in Connecticut, and as such, the supervising physician had to certify that the equipment and personnel meet applicable Connecticut registration and licensure requirements. Precision indicated that, during our audit period, a physician in New York supervised these services and provided a certification from the physician stating that the licenses of technologists and registration of the equipment had been periodically checked to determine that they met all New York State Department of Health requirements. However, Precision did not provide a certification covering our audit period indicating that Connecticut Department of Health registration and licensure requirements had been met.

TRANSPORTATION COSTS NOT PROPERLY PRORATED

Medicare reimburses portable x-ray providers for transporting 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 beneficiaries that received services.¹⁷

For one claim, Precision did not prorate transportation costs in accordance with Medicare requirements. For this claim, Precision claimed Medicare reimbursement for the transportation of equipment for a single beneficiary; however, Precision's documentation indicated that two Medicare beneficiaries received services during the same trip; therefore, transportation costs should have been prorated among two beneficiaries.¹⁸

CONCLUSION

On the basis of our sample results, we estimated that Precision improperly received at least \$332,233 in Medicare reimbursement for portable x-ray services that did not comply with certain Medicare requirements for the audit period. This overpayment amount includes payment dates that are outside of the 3-year recovery period. Of the total estimated overpayments, at least \$120,628 was within the 3-year recovery period, and as much as \$211,605 was outside the 3-year recovery period.

RECOMMENDATIONS

We recommend that Precision:

- refund \$120,628 to the Federal Government for portable x-ray services that did not comply with Medicare requirements and that are within the 3-year claims recovery period;
- work with the MACs to return overpayments outside of the 3-year claims recovery period, which we estimate to be as much as \$211,605 for our audit period, in accordance with the 60-day repayment rule; and

¹⁷ *Medicare Claims Processing Manual*, chapter 13, § 90.3.

¹⁸ For this service, we questioned the difference in Medicare reimbursement between what was claimed and what was eligible for reimbursement.

- strengthen its procedures to ensure that it complies with Medicare requirements related to portable x-ray services.

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 and that the order include a statement concerning the condition of the patient which indicates why portable x-ray services are necessary.¹⁹

For all 117 sample claims, Precision believed it complied with this requirement by including a pre-printed statement on each physician's order that read: "Portable x-ray is required due to patient's physical or mental ability to be transported from facility." However, other than a reason for why an x-ray was needed, there was no other patient-specific information on the physician order or other document maintained by Precision that would indicate why portable services were needed.

Based on discussions with CMS officials, the statement that Precision included on the physician order was too general to meet the Medicare requirement that the need for portable services be documented; additional patient-specific information is needed to meet this requirement. According to CMS officials, the intent of this requirement was to have a patient-specific reason that would justify the more costly portable x-ray services.

However, we believe the Medicare requirement that the need for portable x-ray services be included on the physician order is not clear as to how portable x-ray providers are to document that need. Therefore, we are not questioning the sample claims for this reason.

PRECISION HEALTH, INC., COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, Precision, through its attorneys, partially agreed with our recommendations. Specifically, Precision stated that most of its claims for portable x-ray services complied with Medicare payment rules. Of the 59 claims questioned in our draft report, Precision agreed that 8 did not comply with Medicare requirements. However, it disagreed—either fully or in part—with our determinations for the remaining 51 claims and provided detailed explanations as to why these claims complied with Medicare requirements, as well as additional documentation for other claims.

Precision also 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 Precision during our audit period. Precision 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 Precision, extrapolation would only be lawful if our review demonstrated a sustained or high level of payment error, as our draft report did not indicate that

¹⁹ 42 CFR § 486.106(a)(2).

the errors were the result of a failed educational intervention. Based on its contention that only eight sample claims did not comply with Medicare requirements, Precision stated that such an error rate would not rise to the high level of payment error required by the statute to support extrapolation. Finally, Precision stated that it would repay the eight claims that it agreed were in error. However, Precision does not believe it has any repayment obligation for the remaining claims because those claims complied with Medicare coverage conditions for portable x-ray services and therefore, are not subject to the 60-day repayment rule. Precision's comments are included as Appendix D.²⁰

After reviewing Precision's comments and additional documentation, we revised our determinations for 37 claims. Specifically, we are no longer questioning 25 claims for which services were not ordered in accordance with Medicare requirements, 8 claims for which the performing technician was not identifiable, 7 claims for which physician supervision requirements were not met, and 7 claims that contained services provided by unqualified technicians. The total exceeds 37 because 9 of the claims had more than 1 deficiency that we are no longer questioning. We revised our report and recommendations accordingly; however, for 7 of the 37 claims for which we revised our determinations, the claims remain unallowable for other reasons.

We disagree with Precision's contention that the number of claims in error does not support extrapolation. The section of the Medicare Modernization Act that Precision cited applies to MACs, not the OIG. In addition, Federal courts have consistently upheld extrapolation as a valid means to determine Medicare overpayments.²¹ Finally, CMS will make the final determination as to the total amount to be refunded and will work with Precision to determine whether it may have liability under the 60-day repayment rule.

SERVICES NOT ORDERED IN ACCORDANCE WITH MEDICARE REQUIREMENTS

Precision Comments

Precision stated that Federal regulations (42 CFR § 410.32) do not require orders for portable x-ray services to include a physician's signature. According to Precision, such a requirement was eliminated from CMS policy guidance several years prior to the start of our audit period. Precision also cited chapter 15, § 80.6.1 of the *Medicare Benefit Policy Manual*, which states that, effective for services on or after January 1, 2003, no signature is required on orders for clinical diagnostic tests paid on the basis of the physician fee schedule. According to Precision, each clinical diagnostic test at issue was paid on the basis of the physician fee schedule; therefore, no physician (or nonphysician practitioner) signature was required on the order or referral for any diagnostic tests performed by Precision.

²⁰ We did not include exhibits submitted as attachments to Precision's comments because they were voluminous. Further, some exhibits contained personally identifiable information.

²¹ 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).

Office of Inspector General Response

Based on our review of Precision's comments and additional documentation, we are no longer questioning 25 of the 39 claims questioned in our draft report because services were not ordered in accordance with Medicare requirements. However, we maintain that portable x-ray services for the remaining 14 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 licensed physician or nonphysician practitioner, and that the order be written and signed by the ordering physician or nonphysician practitioner. The regulation that Precision cited (42 CFR § 410.32) is not applicable to portable x-ray services.²² We maintain that, for 14 claims, Precision claimed Medicare reimbursement for portable x-ray services that were not ordered in accordance with Medicare requirements because the physician's order for portable x-ray services was not signed by a physician or nonphysician practitioner (10 claims) or Precision did not provide a physician order for some services (4 claims).

PHYSICIAN SUPERVISION REQUIREMENTS NOT MET

Precision Comments

Precision stated that our determination that services for one claim were not properly supervised was based on the fact that the physician supervising services provided in Connecticut was not licensed in that State. Precision stated that there is no requirement that the supervising physician be licensed in the State where the portable x-ray services were provided.

Office of Inspector General Response

We questioned the one claim because Precision did not provide any documentation that the supervising physician had certified the equipment used and that the personnel who provided portable x-ray services met applicable State registration and licensure requirements. During our audit period, a physician in New York supervised services provided in Connecticut. However, the only evidence Precision provided to support this was a certification from the supervising physician indicating that he had periodically checked to see if the licenses of technologists and the registration of their equipment met New York State Department of Health requirements. Precision did not provide a physician certification covering our audit period indicating that Connecticut Department of Health registration and licensure requirements had been met. We have revised our report to clarify the reason for disallowing this claim.

²² Specifically, 42 CFR § 410.32(a) explicitly exempts portable x-ray services from the general ordering rules for diagnostic tests and cites the regulations found at 42 CFR § 486.106 as the controlling requirements for portable x-ray services.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our review covered 97,279 claims for which Precision received Medicare reimbursement totaling \$7,829,074 for portable x-ray services provided during our audit period. A claim consisted of all payments made to Precision 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 Precision'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 Precision'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 August 2013 through May 2015.

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 Precision officials to gain an understanding of Precision'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 97,279 claims for portable x-ray services, totaling \$7,829,074, for the period January 1, 2011, through October 31, 2012;
- selected a stratified random sample of 117 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 of the sample claims 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 97,279 claims;
- estimated the unallowable Medicare reimbursement paid in the sampling frame of 97,279 claims that is within the 3-year recovery period;
- calculated the overpayments that were outside the 3-year recovery period; and
- discussed the results of our review with Precision officials.

See Appendix B for the details of our statistical sampling methodology and Appendix C 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: STATISTICAL SAMPLING METHODOLOGY

POPULATION

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

SAMPLING FRAME

The sampling frame was an Access database containing 97,279 portable x-ray service claims, totaling \$7,829,074 paid to Precision for services provided during our audit period. A claim consisted of all payments made to Precision for portable x-ray services provided to a beneficiary on the same date of service. The claims data was 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 Precision for portable x-ray services provided during the period January 1, 2011, through October 31, 2012. To accomplish this, the portable x-ray service claims were separated into two strata, as follow:

Stratum	Stratum Range	Number of Claims	Medicare Paid Amount
1	Less than \$600	97,262	\$7,814,303
2	Greater than or equal to \$600	17	14,771
TOTALS		97,279	\$7,829,074

SAMPLE SIZE

We selected a sample of 117 claims, as follows:

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

SOURCE OF RANDOM NUMBERS

We generated random numbers with the Office of Inspector General, Office of Audit Services 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 17 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 Precision during our audit period, and the amount of overpayments paid within the 3-year recovery period, at the lower limit of the 90-percent confidence interval. We also estimated the overpayment amount outside the 3-year recovery period. To calculate this amount, we subtracted the lower limit of the overpayments within the 3-year recovery period from the lower limit of the total overpayments.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

TOTAL MEDICARE OVERPAYMENTS FOR THE AUDIT PERIOD

Sample Details and Results

Stratum	Claims in Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Claims	Value of Unallowable Claims
1	97,262	\$7,814,303	100	\$7,917	18	\$915
2	17	14,771	17	14,771	11	6,554
Total	97,279	\$7,829,074	117	\$22,688	29	\$7,469

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

Point estimate	\$896,803
Lower limit	332,233
Upper limit	\$1,461,373

MEDICARE OVERPAYMENTS FOR CLAIMS PAID WITHIN 3-YEAR RECOVERY PERIOD

Sample Details and Results

Stratum	Claims in Frame	Value of Frame	Sample Size	Value of Sample	No. of Unallowable Claims	Value of Unallowable Claims
1	97,262	\$7,814,303	100	\$7,917	10	\$603
2	17	14,771	17	14,771	6	2,661
Total	97,279	\$7,829,074	117	\$22,688	16	\$3,264

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

Point estimate	\$589,424
Lower limit	120,628
Upper limit	\$1,058,219

APPENDIX D: PRECISION HEALTH, INC., COMMENTS



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RE: **Precision Health, Inc.'s Response to
DHHS, OIG Draft Audit Report No. A-02-13-01038**

Dear Ms. Griffis:

The enclosed correspondence is being submitted on behalf of Precision Health, Inc. ("Precision Health") in response to the U.S. Department of Health and Human Services, Office of Inspector General's ("OIG") draft report, *"Precision Health, Inc., Improperly Claimed Medicare Part B Reimbursement for Portable X-ray Services"* (the "Draft Report"). Our firm was engaged to assist Precision 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 January 8, 2016 submission deadline. We appreciate your careful consideration of the enclosed response.

By way of background, Precision 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 117 claims from a universe of 97,279 claims for portable x-ray services provided to beneficiaries with Part B coverage during the time period of January 1, 2011, through October 31, 2012. The stratification consisted of two strata which included (i) 100 claims for which the payment was less than \$600, and (ii) 17 claims for which the payment was greater than or equal to \$600. The review identified 59 claims that allegedly did not comply with the Medicare payment requirements. The amount paid on the 59 claims was \$12,588; however, based on an extrapolation of the error rate to the universe of claims the identified overpayment amount was \$1,573,301.

Upon receipt of the Draft Report, Precision 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

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associated Precision Health patient records, which were prepared in the normal course and have been maintained on file. In addition to records that Precision Health is required to prepare and maintain, Precision Health obtained additional patient records from the referring provider where appropriate to support payment for the claim. The spreadsheet provided by the OIG that identified the claims that were allegedly paid in error was revised by adding a column to include "Rebuttal Comments" for each claim line item and a column "Revised Amount Questioned" to indicate when Precision 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. In the Rebuttal Comments on the enclosed spreadsheet,¹ the corresponding enclosed patient records,² records which were contemporaneously created at the time services were ordered and rendered and which confirm Precision Health's adherence to Medicare's payment rules, are identified via the use of numbered tabs. [Exhibit 1.] The patient records and legal analyses confirm that the vast majority of the claims complied with the 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, which provides an overview of the applicable Medicare coverage rules for portable x-ray testing, there is an incorrect reference to the need for a "signed physician order."³ Accordingly, for 32 claims, payment for the portable x-ray services were denied as the order "was signed by nursing home staff—not the ordering physician." These statements 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.

¹ Precision Health is providing two versions of the claims spreadsheet, *i.e.*, a paper copy that includes beneficiary information and an electronic copy on the CD that has beneficiary information redacted to allow the OIG to publish the spreadsheet.

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

³ In the Background section of the Draft Report, footnote 6 cites to the Medicare regulations at 42 CFR § 486.106(b) as the rule that requires a signed physician order for portable x-ray services. As explained below, these are outdated rules that CMS simply did not modify when the signature requirement was removed.

As discussed more fully below, 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, federal regulations were adopted setting forth the conditions that must be satisfied in order to receive payment from Medicare for diagnostic testing, including diagnostic x-rays. These particular regulations at 42 C.F.R. § 410.32 expressly address portable x-ray services. Most importantly, when adopting the 1968 regulations, CMS cited to the same enabling statute⁴ that provided the statutory basis for the regulations at 42 C.F.R. § 410.32. 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 litigation⁵ which is discussed more fully below, CMS amended the regulations at 42 C.F.R. § 486.106 (setting forth the 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 physician orders at 42 C.F.R. § 410.32 do not include any requirement for a physician signature on the order for a portable x-ray test.

In its policy guidance, many years ago CMS eliminated any requirement for a physician's or nonphysician practitioner'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 particular, Subsection 80.6.1 of Chapter 15 the Medicare Benefit Policy Manual ("MBPM") expressly states, "No signature is required on orders for clinical diagnostic tests paid on the basis of . . . the physician fee schedule."⁶ [Exhibit 2.] Since this CMS policy was

⁴ Section 1861(s)(3) of the Social Security Act [42 U.S.C. § 1395x(s)(3)].

⁵ The litigation involved appeals of overpayment recoupments in which Medicare Administrative Contractors ("MACs") were applying the 1968 regulatory requirements 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. Precision Health was involved in that litigation and has enclosed a decision in which the Administrative Law Judge concurred that the more recently adopted regulations at 42 C.F.R. § 410.32 control.

⁶ 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

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 Precision Health.

Furthermore, 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.⁷ [Exhibit 3.]

Based on the application of the controlling law, any decision to deny a claim based on the lack of the signature of the physician or the nonphysician practitioner on the order should be reversed. Although Precision Health understands that the physician's or nonphysician practitioner's signature is not required, it has nevertheless enclosed a signed order where one was obtained from the referring provider. As noted above, some of these additional patient records were obtained after Precision Health provided patient records to the OIG to review for this audit. Refer to the patient records in Exhibit 1.

MEDICARE LAWS REQUIRE COVERAGE FOR PORTABLE X-RAY TESTS BASED UPON THE ORDER OR REFERRAL OF A NURSE PRACTITIONER

Under similar reasoning, page three of the Draft Report incorrectly states "portable x-ray services must be ordered by a licensed doctor of medicine or doctor of osteopathy."⁸ Accordingly, for a number of the diagnostic tests at issue, the reviewer denied payment for the test because the test was ordered by a nurse practitioner. As noted above, CMS modified its rules over time regarding who is authorized to order diagnostic tests, including portable x-ray testing, allowing such tests to be ordered by nurse practitioners.

Internet-only MBPM to include the requirements for physician orders for diagnostic tests formerly contained in Section 15021 of the MCM.

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

⁸ In the Background section of the Draft Report, footnote 10 cites to the Medicare regulations at 42 CFR § 486.106(a) as the rules that require an order from a doctor of medicine (M.D.) or doctor of osteopathy (D.O.). As explained below, these are outdated rules that CMS simply did not modify when it expanded the definition of physician or provided new rules to allow orders from nonphysician practitioners. Subsequent to litigation discussed below, CMS modified these older regulations to expressly state that nonphysician practitioners are authorized to order portable x-ray tests.

The Medicare regulations specific to ordering portable x-rays at 42 C.F.R. § 486.106, which were adopted in 1968 and are discussed more fully below, included the requirement that the diagnostic tests be ordered by a physician. When these regulations were promulgated, the Medicare statute defined physician to only include an M.D. or D.O, and Medicare's definition was incorporated into the 1968 regulations. Subsequent to the promulgation of these regulations, the Medicare statute was amended to broaden the definition of "physician" and currently defines "physician" to additionally include dentists, podiatrists, and optometrists, and chiropractors. 42 U.S.C. § 1395x(r). When Congress enacted this statutory change it included language to require this revised definition of physician be used in "connection with the performance of any function or action."

Additionally, the Medicare statutes do not expressly address who has the authority to order portable x-ray tests. With respect to diagnostic x-ray services furnished where the patient resides, which include portable x-ray services, the Medicare statute simply requires that the testing be performed under the supervision of a physician. Specifically, the Medicare statute defines certain covered medical and other health care services, to include:

diagnostic X-ray services (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).

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, or between x-rays ordered by nonphysician practitioners and those ordered by physicians. Nor has Congress ever suggested that Medicare does not cover portable x-rays ordered by a nonphysician practitioner.

Significantly, within the same section of the Medicare statute where diagnostic x-ray services are discussed, Congress amended the Medicare statute to provide coverage for medical services performed by physician assistants, nurse practitioners and clinical nurse specialists (collectively, nonphysician practitioners or NPPs). Specifically, Congress provided for the coverage of medical services by NPPs that would otherwise be covered physician services:

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(K)(i) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a physician assistant (as defined in subsection (aa)(5)) under the supervision of a physician (as so defined) and which the physician assistant is legally authorized to perform by the State in which the services are performed . . . ,

(ii) services which would be physicians' services and services described in subsections (ww)(1) and (hhh) if furnished by a physician (as defined in subsection (r)(1)) and which are performed by a nurse practitioner or clinical nurse specialist (as defined in subsection (aa)(5)) working in collaboration (as defined in subsection (aa)(6)) with a physician (as defined in subsection (r)(1)) which the nurse practitioner or clinical nurse specialist is legally authorized to perform by the State in which the services are performed, and such services . . .

42 U.S.C. § 1395x(s)(2)(K)(emphasis added).⁹ [Exhibit 4.]

Congress did set forth certain parameters for NPP services, including (i) supervision of physician assistants and collaboration between nurse practitioners and physicians; and, (ii) requiring NPPs to adhere to the scope of practice outlined by state law. State practice acts routinely include the ordering of diagnostic tests as within the scope of practice for NPPs. The applicable state laws related to a nurse practitioner's scope of practice appear below. Thus, by adopting these provisions, Congress enabled NPPs to provide physician services, included ordering diagnostic tests, such as portable x-rays.

More recently, Medicare regulations were adopted setting forth the conditions that must be satisfied in order to receive payment for diagnostic testing, including diagnostic x-rays. These particular regulations at 42 C.F.R. § 410.32 address portable x-ray services and orders by NPPs for diagnostic tests. Most notable, these regulations were adopted under the same enabling statute that provided for the adoption of the conditions for payment regulations discussed above. Specific to the issue of orders by NPPs, the regulations specify:

Application to nonphysician practitioners. Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit,

⁹ These particular Social Security Act Amendments were included in the Balanced Budget Act of 1997.

may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.
42 C.F.R. § 410.32(a)(2). [Exhibit 5.]

The conditions for payment specific to portable x-ray tests include requirements for the qualifications of the supplier, physician supervision requirements, and covered procedures, but place no prohibition against an NPP ordering the testing. Specifically, the conditions for coverage of portable x-ray services require:

Portable x-ray services. Portable x-ray services furnished in a place of residence used as the patient's home are covered if the following conditions are met:

- (1) These services are furnished under the general supervision of a physician, as defined in paragraph (b)(3)(i) of this section.
 - (2) The supplier of these services meets the requirements set forth in part 486, subpart C of this chapter, concerning conditions for coverage for portable x-ray services.
 - (3) The procedures are limited to –
 - (i) Skeletal films involving the extremities, pelvis, vertebral column, or skull;
 - (ii) Chest or abdominal films that do not involve the use of contrast media; and
 - (iii) Diagnostic mammograms if the approved portable x-ray supplier, as defined in subpart C of part 486 of this chapter, meets the certification requirements of section 354 of the Public Health Service Act, as implemented by 21 CFR part 900, subpart B.
- 42 C.F.R. § 410.32(c). [Exhibit 5.]

As noted above, CMS' commentary when adopting and revising these conditions for payment is insightful on the issue of orders provided by NPPs. In the preamble to the final regulations published on November 22, 1996, CMS stated:

Further, certain nonphysician practitioners who provide services that would be physician services if furnished by a physician under a specific enumerated benefit in the statute would be treated the same way as the physician treating the beneficiary for the purpose of this section. Nonphysician practitioners who meet this definition are physician assistants (section 1861(s)(2)(K)(i) of the Act), nurse practitioners (section 1861(s)(2)(K)(ii) of the Act), clinical nurse specialists (section 1861(s)(2)(K)(iii) of the Act), nurse-midwives (sections 1861(s)(2)(L) and

1861(gg) of the Act), clinical psychologists (sections 1861(s)(2)(M) and 1861(ii) of the Act), and clinical social workers (sections 1861(s)(2)(N) and 1861(hh) of the Act) operating within the scope of their statutory benefit and State licenses.
61 Fed. Reg. 59490, 59497. [Exhibit 6.]

CMS has additionally clarified that although NPPs are treated similar to physicians with regard to ordering diagnostic testing, NPPs do not have the same status as physicians with respect to the supervision of the actual diagnostic testing. When CMS was asked to clarify the relationship between the requirement for physician supervision and the ability for NPPs to order tests, CMS clarified the distinction between ordering and performing the testing as follows:

Comment: One commenter requested clarification of the interaction between the ordering of tests by nonphysician practitioners and the coverage requirement for direct physician supervision of the performance of x-rays and other diagnostic tests.

Response: While nonphysician practitioners are permitted to order diagnostic tests under certain conditions, this does not eliminate the requirement for physician supervision.
Id. at 59498. [Exhibit 6.]

Since the initial language continued to create confusion between this distinction for ordering versus supervising, on October 31, 1997, CMS amended the regulation to clarify that NPPs are treated the same as physicians with regard to ordering but not supervising the diagnostic services. In the preamble discussion to the final rule, CMS reiterated this distinction, stating:

Therefore, we are modifying the wording of Sec. 410.32(a)(3) to change the last word from "section" to "paragraph." In other words, the nonphysician practitioners are treated as physicians as far as the ordering of tests for the patients they are treating is concerned but not for the other subject of Sec. 410.32, that is, the supervision of the performance of tests.
62 Fed. Reg. 59048, 59058. [Exhibit 7.]

This same principle was reiterated in the preamble to the final rules, which focused in part on the performance and supervision of diagnostic tests by NPPs, published on November 2, 1999. In responding to comments raised in response to the proposed regulation changes, CMS stated:

We received many comments opposing the proposal to modify Sec. 410.32 to permit NPs and CNSs to order, interpret, and perform radiological procedures without physician supervision when they are authorized by the State to perform these services. Our proposal addressed only the last activity. The legal authority for NPs and CNSs to order and to interpret tests (and for PAs to perform these activities under physician supervision) is not at issue. Section 410.10(a)(3) already provides that nonphysician practitioners (including PAs, NPs, and CNSs) who are operating within the scope of their authority under State law may order diagnostic tests. With regard to the interpretation of diagnostic tests, Congress has specifically recognized the ability of PAs, NPs, and CNSs to furnish services that would be physician services, if furnished by a physician, subject to the provisions of State law.
64 Fed. Reg. 59380, 59415. [Exhibit 8.]

This is not the only comment by CMS deferring to Congress granting statutory authority for NPPs to have a role with regard to diagnostic testing. Later in the same preamble discussion, responding to another comment, CMS emphatically stated that it would not interfere with Congressional intent in determining the permitted scope of practice of NPPs in relation to diagnostic tests:

As indicated in the July 1999 proposed rule, we made the proposals to remove the requirement for physician supervision of NPs and CNSs for diagnostic tests for services NPs and CNSs are authorized to perform under State law and to establish a level of general supervision by a physician for diagnostic tests that PAs are authorized to perform under State law. Further, since we have not imposed requirements regarding specific training requirements for physician specialties to be able to perform and bill for these diagnostic tests, we believe that it is inappropriate to apply these requirements to practitioners whom the Congress has specifically recognized as having the ability to furnish services that would be physician services if furnished by a physician, subject to the provisions of State law. The Medicare law generally leaves the scope of practice of NPs, CNSs, and PAs to be determined by the individual States. Finally, we have no indication that NPs and CNSs will abuse their benefit by trying to perform diagnostic tests they are not qualified to do.
Id. [Exhibit 8.]

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At no time in relation to the adoption of Section 410.32 was an intention ever expressed that there would be a limitation that prohibits NPPs from ordering diagnostic tests simply because they are portable x-rays, as a result of the wording of a regulation adopted 30 years earlier when there were no such NPPs services.

Thus, it is apparent that the regulations at Sections 410.32 and 486.106 must be read together, taking into account the Congressional authority that enabled CMS to adopt these regulations and Congresses' intent for NPPs to order diagnostic x-rays under the Medicare statute. The diagnostic testing regulation has a specific provision referring to portable x-rays under Section 410.32(c) that, as a later-adopted regulation, must be read together with Section 486.106 as it was crafted in 1968. Under the principles of statutory construction, it would not be an appropriate reading of the regulations as a whole for an x-ray supplier condition of coverage adopted in 1968 to be interpreted to limit a more specific condition for payment regulation applicable to NPPs which was adopted consistent with the enabling statute for both regulations.

CMS' own interpretive guidance of its regulations further requires coverage for portable x-ray tests ordered by NPPs. CMS has repeatedly and consistently honored claims for payment for portable x-ray services ordered by NPPs. In particular, the following CMS interpretive guidance was in effect for the time period at issue in this audit:

- Section 80.3.2.1.3 of Chapter 1 of the Medicare Claims Processing Manual ("MCPM") provides that a claim must be returned to the provider "as unprocessable . . . 1. For portable x-ray services claims, if the ordering physician, physician assistant, nurse practitioner, clinical nurse specialist's name, and/or . . . NPI . . . is not entered in items 17 . . . or if the NPI is not entered in item 17b. of the Form CMS-1500(8/05) . . ." MCPM, CMS Pub. 100-04, Ch. 1 § 80.3.2.1.3. [Exhibit 9.] If NPPs were not entitled to order portable x-ray tests, there would be no reason for CMS to instruct its contractors that the NPP's name and National Provider Identification or NPI number must be listed on the claim form in the data fields to enter information for the individual who ordered the service. This excerpt serves as clear evidence of CMS' prior interpretation of the rule.
- Chapter 15, Section 80.4 of the MBPM addresses coverage for portable x-rays, but nowhere does that section require that the portable x-ray be ordered by a doctor, as opposed to an NPP. MBPM, CMS Pub. 100-02, Ch. 15 § 80.4. [Exhibit 10.] Moreover, Section 80.6 of the MBPM addresses diagnostic tests generally (including portable x-rays). Section 80.6 defines the term "Treating

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Practitioner” to include “a nurse practitioner, clinical nurse specialist, or physician assistant, as defined in § 1861(s)(2)(K) of the Act, who furnishes, pursuant to State law, a consultation or treats a beneficiary for a specific medical problem, and who uses the result of a diagnostic test in the management of the beneficiary’s specific medical problem.” The definition of the term “Order” further confirms that “treating practitioners” may order diagnostic tests, including portable x-rays, stating: “An ‘order’ is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a beneficiary” and “may be delivered via . . . [a] written document signed by the treating physician/practitioner . . . [a] telephone call by the treating physician/practitioner . . . [or a]n electronic mail by the treating physician/practitioner.” MBPM, CMS Pub. 100-02, Ch. 15 § 80.6.1 (emphasis added). [Exhibit 2.]

- Section 20.3.2(D)¹⁰ of Chapter 13 of the MCPM provides: “There are two requirements for all diagnostic tests under § 1861(s)(3) of the Act, as implemented by 42 CFR§410.32 and [other documents]. Namely, the test must be ordered by the treating practitioner, and the test must be supervised by a physician.” MCPM, CMS Pub. 100-04, Ch. 13 § 20.3.2(D) (emphasis added). [Exhibit 11.] This section does not exclude portable x-ray tests or indicate in any way that they should be treated differently.
- In conjunction with the Medicare regulations at 42 C.F.R. § 424.507, requiring the National Provider Identifier (“NPI”) number of the ordering or referring provider to be included on a claim for radiologic testing, regulations which became statutory requirements by the Affordable Care Act, CMS published a series of educational documents in June 2010, to assist providers and suppliers to comply with this requirement, documents that were updated through June 2012. In particular, CMS posted on its website and distributed a circular entitled “Medicare Enrollment Guidelines for Ordering/Referring Providers” that states: “Only Medicare-enrolled individual physicians and non-physician practitioners of a certain specialty type may order/refer for Part B (including Portable X-Ray services) . . . These individuals include: . . . Physician Assistant, Certified Clinical Nurse Specialist, Nurse Practitioner . . .” “Medicare Enrollment Guidelines for Ordering/Referring Providers,” ICN 906223 (June 2012)(emphasis added); *see, e.g.*, “Edits on the Ordering/Referring Providers in Medicare Part B Claims,” MLN Matters Number SE1011 (June 2010); “Phase 2 of Ordering and Referring

¹⁰ This Section was formerly Section 20.2.4.2. Transmittal 1931 provided for the relocation to Section 20.3.2.

Requirement," MLN Matters Number SE1221 (June 2012). [Exhibit 12.]. Thus, CMS repeatedly and consistently from June 2010 through June 2012, published guidance that explicitly authorizes "nonphysician practitioners" to order portable x-ray tests.

As discussed above, Medicare requires a nurse practitioner ("NP") to comply with the authority granted under the respective state practice act. The practice act in New Jersey authorizes NPs to diagnose medical conditions, expressly allowing NPs to order diagnostic tests. The practice act in New York also authorizes NPs to diagnose medical conditions, which implicitly allows an NP to order a diagnostic test. Therefore, ordering portable x-ray tests are included in the NP scope of practice in both states. In particular, the practice acts provide:

In addition to all other tasks which a registered professional nurse may, by law, perform, an advanced practice nurse may manage preventive care services, and diagnose and manage deviations from wellness and long-term illnesses, consistent with the needs of the patient and within the scope of practice of the advanced practice nurse, by:

- (1) initiating laboratory and other diagnostic tests;
- (2) prescribing or ordering medications and devices, as authorized by subsections b. and c. of this section; and
- (3) prescribing or ordering treatments, including referrals to other licensed health care professionals, and performing specific procedures in accordance with the provisions of this subsection.

N.J. Stat. Ann. § 45:11-49.10.a.

The practice of registered professional nursing by a nurse practitioner, certified under section six thousand nine hundred ten of this article, may include the diagnosis of illness and physical conditions and the performance of therapeutic and corrective measures within a specialty area of practice, in collaboration with a licensed physician qualified to collaborate in the specialty involved, provided such services are performed in accordance with a written practice agreement and written practice protocols . . .

N.Y. Educ. Law § 6902.3.a.i.

In December 2011, the OIG issued a report entitled, "Questionable Billing Patterns of Portable X-Ray Suppliers." Department of Health and Human Services, Office of Inspector General, No. OEI-12-10-00190 (Dec. 2011)(hereinafter, the "OIG 2011 Report"). That report purported to find that "[t]wenty portable x-ray suppliers

exhibited questionable billing patterns,” and asserted that “42 C.F.R. § 486.106 requires that portable x-rays be ordered by a physician, defined by that regulation as a licensed medical doctor or doctor of osteopathy.” *Id.* at ii and 2. The OIG 2011 Report did not, however, mention the enabling Medicare statute nor did it address the later adopted 1997 regulations discussed above, that were adopted under the same statutory authority and expanded who could order portable x-rays tests to include NPPs among others. In response to the Inspector General’s recommendation, CMS instructed its MACs to recoup the alleged overpayments for portable x-ray services not ordered by M.D.s or D.O.s, including tests ordered by NPPs. On appeal to Administrative Law Judges, those overpayment cases have been routinely resulted in a reversal. We are enclosing, as a representative case, one such favorable decision for Precision Health, in which the Administrative Law Judge found “the current, updated law more relevant than the outdated law” and that the “New York State law, and the regulations intend for portable x-rays to be ordered by NPPs.” *Appeal of Precision Health, Inc.*, DHHS, OMHA, ALJ Appeal No. 1-1517240581. [Exhibit 13.]

To recap:

- The controlling federal statute provides that covered medical services include diagnostic x-ray tests (of which portable x-ray tests are a subset), which would be covered medical services when performed by a physician, must be considered covered medical services when performed by NPPs, which includes nurse practitioners.
- The Medicare regulations at 42 C.F.R. § 410.32(a)(2), promulgated in 1997, provide that “[n]onphysician practitioners . . . who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare benefit, may be treated the same as physicians treating beneficiaries.” Section 410.32(a) authorizes physicians to order “[a]ll diagnostic x-ray tests.” 42 C.F.R. § 410.32(a) (emphasis added). Read together, these 1997 provisions granted NPPs the authority to order “all diagnostic x-ray tests,” including portable x-ray tests.
- Coverage is consistent with CMS’ own published guidance which has affirmed to portable x-ray suppliers that CMS would cover and pay for portable x-rays services ordered by NPPs.
- For approximately 18 years, CMS has been providing coverage for and paying portable x-ray suppliers for services ordered by NPPs.
- The respective state law scope of practice authorized NPPs to order diagnostic tests, including portable x-ray tests.

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- Recent cases, decided by Administrative Law Judges reviewing the same legal analysis provided above, decided that the Medicare coverage rules do include coverage for portable x-ray tests ordered by NPPs.

Based on the application of the controlling law, any decision to deny payment of any claim due to the fact that the diagnostic test was ordered by an NP must be reversed.

EKG SERVICES WERE PROVIDED BY QUALIFIED TECHNICIANS

In the Draft Report, seven (7) claims for electrocardiogram ("EKG") services were denied alleging that the technicians who performed these test were not Qualified Technicians as required by the regulations. We believe that the reviewers may have applied the requirements for an EKG performed by an Independent Diagnostic Testing Facility ("IDTF"), which are not applicable to testing performed by a portable x-ray supplier. The technicians that performed the EKGs were "Qualified Technicians" under the conditions for coverage for portable x-ray suppliers.

Historically, portable x-ray suppliers were approved to not only provide certain diagnostic radiology testing, but to additionally provide electrocardiogram ("EKG") tracings. CMS simply has not provided any specific educational requirements, certification, or any other approval needed for technicians who perform EKG testing for a portable x-ray supplier.

The regulations at 42 C.F.R. § 486.100, Subpart C, set forth the conditions for coverage of portable x-ray services. In particular, the regulations in Section 486.104 include the "personnel qualification requirements," requirements which include health standards and some safety standards. With regard to EKG technologists, the following standards apply:

- (1) Each employee is qualified for his or her position by means of training and experience; and
 - (2) Employees receive adequate health supervision.
- 42 C.F.R. § 486.104(c). [Exhibit 14.]

The conditions for coverage also include requirements for orientation for all personnel and specific qualification standards for x-ray technologists; however, there are no additional standards for technologists that perform EKG services. And, the focus of the safety standards at 42 C.F.R. § 486.108 is aimed at reducing radiation exposure. There simply are no specific safety standards for EKG testing.

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In its interpretive guidance, CMS merely reiterates the language in the regulations without providing any further detail. In particular, CMS instructs:

Portable x-ray suppliers must ensure: (i) the health and safety standards are met, and (ii) the technician meets "the personnel qualification requirements in the conditions for coverage of portable x-ray services." MBPM, CMS 100-02, Ch. 15 §§ 80.4.5 and 80.4.2. [Exhibit 10.]

Furthermore, the Medicare State Operations Manual (the manual that sets forth the interpretive guidance for state surveyors to determine a portable x-ray supplier's compliance with the regulations) only requires the state surveyors to ensure that the requirements in the conditions for coverage for portable x-ray suppliers are met. And, in the states in which Precision Health operates, there simply is no state licensure, certification, registration, or other approval that is required to perform EKG testing. All of the Precision Health staff members who perform EKG testing have received appropriate training and experience and health supervision as required under the regulations. As further evidence of Precision Health's compliance with these conditions, Precision Health has never received any survey citation for having EKG testing performed by technicians who have not met the personnel qualification requirements or the health and safety standards.

As noted above, we believe the reviewers may have applied the IDTF standards when reviewing Precision Health's claims. Unlike the portable x-ray rules, the Medicare regulations setting forth the IDTF qualification standards at 42 C.F.R. § 410.33, require that:

Any nonphysician personnel used by the IDTF to perform tests must demonstrate the basic qualifications to perform the tests in question and have training and proficiency as evidenced by licensure or certification by the appropriate State health or education department. In the absence of a State licensing board, the technician must be certified by an appropriate national credentialing body. The IDTF must maintain documentation available for review that these requirements are met. 42 C.F.R. § 410.33(c). [Exhibit 15.]

Therefore, the IDTF rules require certification by a national credentialing body for EKG technicians, even in the absence of state licensure. These same standards do not, however, apply to portable x-ray suppliers. For this reason, any claim for which

payment was denied due to not being performed by Qualified Technicians must be reversed.

PERFORMING TECHNICIAN IS IDENTIFIABLE

In the Draft Report, eight (8) claims were denied based on a finding that there was insufficient "evidence to identify the technician that provided the services" since the records provided to be reviewed "did not clearly identify the name of the technician that performed the x-ray." The Draft Report further noted some concern regarding conflicting information and documentation related to who actually performed the testing. For each claim where there was a question regarding the identification of the technician who provided the services, enclosed with the patient records are logs (titled "Preliminary Report" in which the technician who performed the diagnostic test/s identifies the test/s that were performed. These logs, which are completed when services are rendered, clearly confirm the identity of the technician. Since these are business records that are not incorporated with the patient records that Precision Health maintains, the records were not provided to the OIG when patient records were submitted for review in this audit. Refer to the Rebuttal Comments in the spreadsheet and the tabbed items contained in Exhibit 1. Therefore, any claim denied on the basis that the identity of the technician could not be confirmed must be reversed.

PHYSICIAN SUPERVISION REQUIREMENTS WERE MET

In the Draft Report, seven (7) claims were denied alleging "the supervising physician did not ensure that the performing technicians met applicable Federal, State, and local licensure requirements." Refer to the section above "EKG Services Were Provided by Qualified Technicians" for Precision Health's confirmation that the EKG technicians met the applicable requirements for services provided by a portable x-ray supplier. The supervising physician did, therefore, ensure that Qualified Technicians performed the EKG testing.

In the Draft Report, one (1) claim was denied alleging "there was no documentation that the services were supervised by a licensed physician." This particular comment relates to services provided for a beneficiary that resides in Connecticut and is based on a determination that Precision Health had no supervising physician who was licensed in Connecticut when the services were provided. Once again, we believe that the reviewers may have applied the requirements for physicians supervising testing by an IDTF, not a portable x-ray supplier.

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The portable x-ray supplier regulations are silent with regard to services provided by suppliers that operate in multiple states. The standards for the qualifications of the supervising physician simply require that:

Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he (1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or (2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or (3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

42 C.F.R. § 486.102(b). [Exhibit 14.]

There simply is no requirement in the regulations that the supervising physician needs to be licensed in all of the states in which the portable x-ray supplier operates. With respect to licensure, there is merely the requirement that the supervising physician be licensed.

CMS' interpretive guidance related to the qualification of the supervising physician further substantiate that the rules for a portable x-ray supplier do not require the physician to be licensed in every state, or in any state for that matter, in which the supplier operates. In particular, CMS instructs the state surveyors to confirm:

[T]hat a physician-supervisor specializes in radiology and is recognized by the medical community as a specialist in radiology (Standard (b)), the record should reflect that the physician is:

- (1) Board certified or board eligible in radiology;
- (2) Board certified or board eligible in a medical specialty which includes advanced training in use of X-rays, e.g., the American Board of Orthopedic Surgery, the American Board of Internal Medicine, the American Board of Physical Medicine and Rehabilitation, and the Board of Thoracic Surgery; or
- (3) Recognized by the medical community as a specialist in radiology. Check the American Medical Directory or the Dictionary of Medical Specialist for (1) and (2).

State Operations Manual ("SOM"), CMS Pub. 100-07, Appendix D (guidance under H0017 interpreting the regulations at 42 C.F.R. § 486.102). [Exhibit 16.]

Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy who is qualified by advanced training and experience in the use of X-rays for diagnostic purposes, i.e., he

(1) is certified in radiology by the American Board of Radiology or by the American Osteopathic Board of Radiology or possesses qualifications which are equivalent to those required for such certification, or

(2) is certified or meets the requirements for certification in a medical specialty in which he has become qualified by experience and training in the use of X-rays for diagnostic purposes, or

(3) specializes in radiology and is recognized by the medical community as a specialist in radiology.

SOM, CMS Pub. 100-07, Appendix D (guidance under H0019 interpreting the regulations at 42 C.F.R. § 486.102(b)). [Exhibit 16.]

Contrast the lack of reference to licensure in the State in which the portable x-ray supplier provided the services in these provisions to the following SOM guidance where CMS expressly requires the physician who orders the test to be licensed in the State in which the services were rendered:

The supplier's records showing that X-ray services were ordered in writing by a physician licensed to practice in the State are essential to establish that the standards are met.

SOM, CMS Pub. 100-07, Appendix D (guidance under H0037 interpreting the regulations at 42 C.F.R. § 486.106). [Exhibit 17.]

Portable X-ray examinations are performed only on the order of a doctor of medicine or doctor of osteopathy licensed to practice in the State.

SOM, CMS Pub. 100-07, Appendix D (guidance under H0038 interpreting the regulations at 42 C.F.R. § 486.106(a)). [Exhibit 17.]

Therefore, CMS clearly distinguished which of the portable x-ray supplier regulations require a physician licensed in the state where services are rendered and which of its regulations simply require the physician to be licensed.

Furthermore, if you contrast the portable x-ray rules to the IDTF rules, the Medicare regulations for IDTFs expressly address situations where the IDTF operates in more than one state and require that:

An IDTF that operates across State boundaries must—

- (i) Maintain documentation that its supervising physicians and technicians are licensed and certified in each of the States in which it operates; and
- (ii) Operate in compliance with all applicable Federal, State, and local licensure and regulatory requirements with regard to the health and safety of patients.

42 C.F.R. § 410.33(e)(1).¹¹ [Exhibit 15.]

Since CMS does not require, for portable x-ray suppliers, that the supervising physician be licensed in the state where services were rendered, the claim that appears to have been denied on the basis the supervising physician was not licensed in the state where the services were rendered must be reversed.

CLAIMS DENIED BASED ON MISSING RECORDS

In the Draft Report, three (3) claims were denied based on the reviewer noting a lack of a physician order for the portable x-ray test. Precision Health's review of the patient records provided to the OIG revealed that the orders were included in the records provided. A copy of the order that was provided to the OIG is enclosed under the corresponding tab in Exhibit 1. The records for these three claims, therefore, support payment for the testing.

In the Draft Report, one (1) claim was denied based on the reviewer noting that no records were provided. Upon review of the claim, Precision Health concurs that the claim was inadvertently submitted with the wrong beneficiary identified. Therefore, even though testing was provided, it was provided for another beneficiary. As soon as this issue was identified during the OIG's audit, Precision Health promptly refunded the payment received and subsequently submitted another claim identifying the correct patient who received the testing. For the reasons discussed below, the amount of the overpayment for this isolated error should not be used to extrapolate to the universe of claims.

¹¹ The associated CMS interpretive guidance is found in Chapter 15 of the Medicare Program Integrity Manual, Section 15.5.19.5 and is specific to IDTFs, not portable x-ray suppliers.

DISCREPANCY REGARDING NUMBER OF VIEWS ON CLAIM AND NUMBER OF VIEWS TAKEN

In the Draft Report, eight (8) claims were noted to have been submitted with a greater number of views than the records indicated had been taken and two claims were noted to have discrepancies between the tests that were ordered and those performed. Precision Health concurs with some of these findings and has indicated those concurrences on the claims spreadsheet enclosed in Exhibit 1. Precision Health has, however, additionally noted on the claims spreadsheet where it disagrees with the amount to be reduced. Where Precision Health concurs with the OIG's findings, it will timely refund the identified payment differential. For the reasons discussed below, the amount of the overpayment should not be used to extrapolate to the universe of claims.

This is the only area where there was more than a single, inadvertent error and Precision Health has focused its efforts on correcting compliance accordingly. In addition to reinforcing the company's performance expectations in a written memorandum to the technologists, Precision Health has been routinely performing quality assurance audits to confirm compliance with the rules. The audit is designed to be a daily sample of twenty percent of the total films taken. In particular, the audit includes a check to confirm that the ordered number of views were performed or documentation exists to explain any deviation from the order.

TRANSPORTATION CHARGES NOT PRORATED PROPERLY

In the Draft Report, the payment amount for one (1) claim was reduced since the reviewer identified that the claim did not include the proper proration among the Medicare patients who received portable x-ray tests during that trip. Precision Health agrees with the OIG's findings and will timely refund the identified payment differential. For the reasons discussed below, the amount of the overpayment for this isolated error should not be used to extrapolate to the universe of claims.

ERROR RATE DOES NOT SUPPORT EXTRAPOLATION

Precision Health respectfully urges that when the above rules are applied to the 59 claims originally determined by the OIG to not comply with the Medicare coverage requirements, the remaining error rate will not support extrapolation to the 97,279 claims in the universe. As noted on the enclosed spreadsheet, Precision 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. Precision Health identified that of the total payment amounting of \$22,688.05 in the claims sample, only \$760.51 was paid in error. For the remaining claims, Precision

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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 18.] 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 MPIM. In particular, Subsection 8.4.1.2 of Chapter 8 of the MPIM¹² indicates 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” (emphasis added). [Exhibit 19.] 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 59 claims at issue demonstrates a “sustained or high level of payment error.”

Precision Health respectfully submits that when the error rate for the SVRS is recalculated to reflect appropriate claims payment determinations based on the evidence in its response to the Draft Report, any remaining isolated payment errors for a particular claim line item will fail to rise to the “identified high level of payment error” required by the statute to support extrapolation.

REPAYMENT OBLIGATION

With respect to the limited number of claims to which Precision Health agrees with the findings in the Draft Report, Precision Health will promptly make repayment. With regard to the remaining claims for which Precision Health has provided Rebuttal Comments disagreeing with the reviewer’s findings, Precision Health does not believe it has any repayment obligation since the claims complied with the conditions for payment and the conditions for coverage for portable x-ray services. Accordingly,

¹² This text was initially placed in Section 3.10.1.2 of Chapter 3 of the MPIM. [Exhibit 19.]

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

Marlyn Griffis, Audit Manager
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January 7, 2016
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Precision Health does not believe that those claims are subject to the 60-day repayment rule cited in footnote eight on page three of the Draft Report.

In closing, Precision Health wishes to thank the OIG for carefully considering its response. Precision Health strives to comply with the Medicare conditions for coverage and believes that the resulting low error rate, after consideration of the legal and factual issues raised in its response, reflects its commitment to do so. Should you have any question or wish to further discuss this response, please do not hesitate to contact us.

Sincerely,

Julie E. Kass

Donna J. Senft

Enclosures

cc: Uri Lerner, President, Precision Health, Inc.

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