

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE COMPLIANCE REVIEW
OF COMMUNITY HOSPITAL**

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Office of Inspector General

<https://oig.hhs.gov>

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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.

Report in Brief

Date: February 2019

Report No. A-05-17-00026

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



Why OIG Did This Review

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and data analysis techniques, we assessed hospital claims based on risk for noncompliance with Medicare billing requirements. For calendar year 2017, Medicare paid hospitals \$206 billion, which represents 55 percent of all fee-for-service payments for the year.

Our objective was to determine whether Community Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

How OIG Did This Review

We selected for review a stratified random sample of 170 inpatient and outpatient claims with payments totaling \$2.8 million for our audit period.

We focused our review on the risk areas that we had identified during prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements.

Medicare Compliance Review of Community Hospital

What OIG Found

The Hospital complied with Medicare billing requirements for 84 of the 170 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 86 claims, all of which were inpatient, resulting in net overpayments of \$1,266,758 for calendar years 2015 and 2016. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$22 million for our audit period.

What OIG Recommends

We recommend that the Hospital refund the Medicare contractor \$22 million (of which \$1,266,758 was net overpayments identified in our sample) in estimated overpayments for the audit period for claims that it incorrectly billed; exercise reasonable diligence to identify and return any additional similar overpayments received outside of our audit period, in accordance with the 60-day rule; and strengthen controls to ensure full compliance with Medicare requirements.

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations. The Hospital agreed that for some claims in the sample, the documentation supports a different level of reimbursement. The Hospital believed that the OIG had no apparent reason to select them for audit, disagreed with all of the findings on the inpatient rehabilitation claims reviewed and believed that we applied the wrong standards, and stated that OIG's sampling methodology was flawed and our use of extrapolation was inappropriate and premature.

After review and consideration of the Hospital's comments, we maintain that all of our findings and the associated recommendations are valid. We submitted the claims selected for review to an independent medical review contractor who reviewed the medical record in its entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements.

The use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on administrative appeal within the Department and in Federal courts.

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INTRODUCTION

WHY WE DID THIS REVIEW

This review is part of a series of hospital compliance reviews. Using computer matching, data mining, and other data analysis techniques, we identified hospital claims that were at risk for noncompliance with Medicare billing requirements. For calendar year (CY) 2017, Medicare paid hospitals \$206 billion, which represents 55 percent of all fee-for-service payments; accordingly, it is important to ensure that hospital payments comply with requirements.

OBJECTIVE

Our objective was to determine whether Community Hospital (the Hospital) complied with Medicare requirements for billing inpatient and outpatient services on selected types of claims.

BACKGROUND

The Medicare Program

Medicare Part A provides inpatient hospital insurance benefits and coverage of extended care services for patients after hospital discharge, and Medicare Part B provides supplementary medical insurance for medical and other health services, including coverage of hospital outpatient services. The Centers for Medicare & Medicaid Services (CMS) administers the Medicare program. CMS contracts with Medicare administrative contractors (MACs) to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

CMS pays hospital costs at predetermined rates for patient discharges under the inpatient prospective payment system. The rates vary according to the diagnosis-related group (DRG) to which a beneficiary's stay is assigned and the severity level of the patient's diagnosis. The DRG payment is, with certain exceptions, intended to be payment in full to the hospital for all inpatient costs associated with the beneficiary's stay.

Hospital Inpatient Rehabilitation Prospective Payment System

Inpatient rehabilitation facilities (IRFs) provide rehabilitation for patients who require a hospital level of care, including a relatively intense rehabilitation program and an interdisciplinary, coordinated team approach to improve their ability to function. Section 1886(j) of the Social Security Act (the Act) established a Medicare prospective payment system for inpatient rehabilitation facilities. CMS implemented the payment system for cost-reporting periods beginning on or after January 1, 2002. Under the payment system, CMS established a Federal prospective payment rate for each of 92 distinct case-mix groups (CMGs). The assignment to a CMG is based on the beneficiary's clinical characteristics and expected resource needs.

Hospital Outpatient Prospective Payment System

CMS implemented an outpatient prospective payment system (OPPS), which is effective for services furnished on or after August 1, 2000, for hospital outpatient services. Under the OPPS, Medicare pays for hospital outpatient services on a rate-per-service basis that varies according to the assigned ambulatory payment classification (APC). CMS uses Healthcare Common Procedure Coding System (HCPCS) codes and descriptors to identify and group the services within each APC group.¹ All services and items within an APC group are comparable clinically and require comparable resources.

Hospital Claims at Risk for Incorrect Billing

Our previous work at other hospitals identified these types of claims at risk for noncompliance:

- inpatient rehabilitation claims,
- inpatient claims billed with high-severity-level DRG codes,
- inpatient claims paid in excess of charges,
- inpatient hospital-acquired conditions and “present on admission”² indicator reporting,
- inpatient medical device credits, and
- outpatient medical device credits.

For the purposes of this report, we refer to these areas at risk for incorrect billing as “risk areas.” We reviewed these risk areas as part of this review.

Medicare Requirements for Hospital Claims and Payments

Medicare payments may not be made for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)). In addition, the Act precludes payment to any provider of services or other person without information necessary to determine the amount due the provider (§ 1833(e)).

¹ HCPCS codes are used throughout the health care industry to standardize coding for medical procedures, services, products, and supplies.

² “Present on admission” refers to diagnoses that are present at the time the order for inpatient admission occurs. Conditions that develop during an outpatient encounter, including emergency department, observation, or outpatient surgery, are also considered present on admission. Acute care hospitals are required to complete the present on admission indicator field on the Medicare inpatient claim for every diagnosis billed.

Federal regulations state that the provider must furnish to the Medicare contractor sufficient information to determine whether payment is due and the amount of the payment (42 CFR § 424.5(a)(6)).

The *Medicare Claims Processing Manual* (the Manual) requires providers to complete claims accurately so that Medicare contractors may process them correctly and promptly (Pub. No. 100-04, chapter 1, § 80.3.2.2). The Manual states that providers must use HCPCS codes for most outpatient services (chapter 23 § 20.3).

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 (60-day rule).³ The Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments.

Community Hospital

The Hospital, which is part of Community Healthcare System, is a 458-bed not-for-profit acute care hospital located in Munster, Indiana. Medicare paid the Hospital approximately \$275 million for 19,098 inpatient and 169,827 outpatient claims for services provided to beneficiaries during CYs 2015 and 2016.

HOW WE CONDUCTED THIS REVIEW

Our audit covered \$40,553,848 in Medicare payments to the Hospital for 2,510 claims that were potentially at risk for billing errors. These claims consisted of inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during CYs 2015 or 2016 (audit period). We selected a stratified random sample of 170 claims with payments totaling \$2,824,623 for review. These 170 claims had dates of service in CY 2015 or CY 2016 and consisted of 165 inpatient and 5 outpatient claims.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and submitted 120 claims to an independent medical review contractor to determine whether the services met medical necessity and coding requirements. This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

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

³ The Act § 1128J(d); 42 CFR part 401 subpart D (the 60-day rule); 42 CFR § 401.305(a)(2)(f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

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.

See Appendix A for the details of our audit scope and methodology.

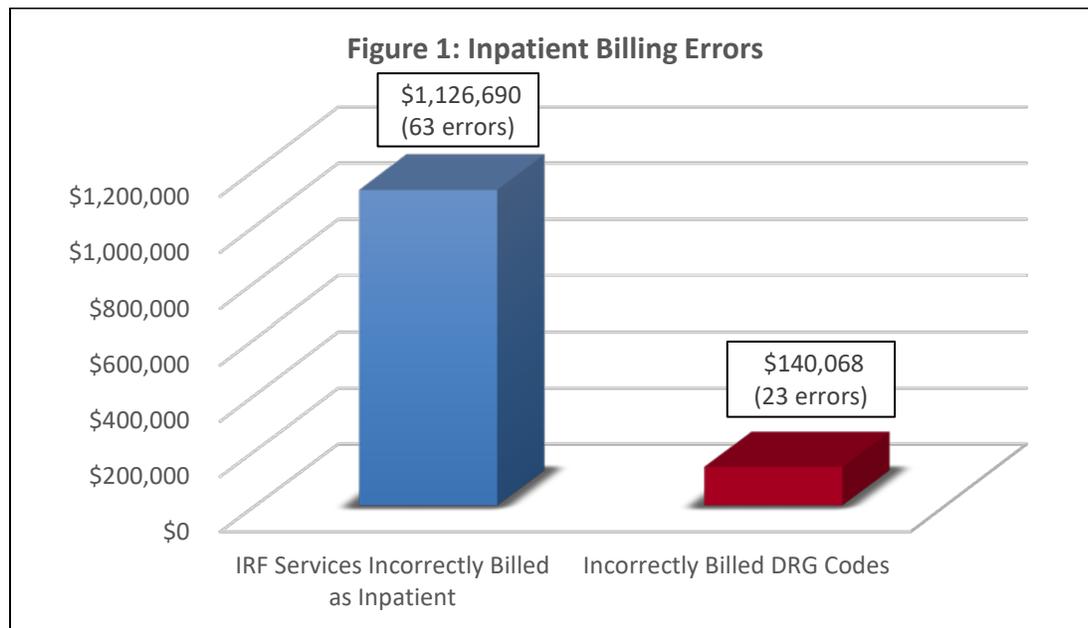
FINDINGS

The Hospital complied with Medicare billing requirements for 84 of the 170 inpatient and outpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 86 claims, all of which were inpatient, resulting in net overpayments of \$1,266,758 for the audit period. These errors occurred primarily because the Hospital did not have adequate controls to prevent the incorrect billing of Medicare claims within the selected risk areas that contained errors.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$22,051,602 for the audit period. See Appendix B for our sample design and methodology, Appendix C for our sample results and estimates, and Appendix D for the results of our review by risk area.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 86 of 165 sampled inpatient claims, which resulted in net overpayments of \$1,266,758, as shown in Figure 1.



Inpatient Rehabilitation Facility Services Incorrectly Billed as Inpatient

Medicare may not pay for items or services that “are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member” (the Act § 1862(a)(1)(A)).

Effective for discharges on or after January 1, 2010, all coverage⁴ and documentation⁵ requirements must be met for IRF care to be considered by Medicare as reasonable and necessary under the Act. If the claim is deemed not reasonable and necessary, the entire payment will be in error.⁶

The *Medicare Benefit Policy Manual* states that the IRF benefit is designed to provide intensive rehabilitation therapy in a resource intensive inpatient hospital environment for patients who, due to the complexity of their nursing, medical management, and rehabilitation needs, require and can reasonably be expected to benefit from an inpatient stay and an interdisciplinary team approach to the delivery of rehabilitation care (Pub. No. 100-02, chapter 1, § 110).

In addition, the *Medicare Benefit Policy Manual* states that for IRF care to be considered reasonable and necessary, the documentation in the patient’s IRF medical record must demonstrate a reasonable expectation that, at the time of admission to the IRF, the patient (1) required the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally required an intensive rehabilitation therapy program; (3) actively participated in, and benefited significantly from, the intensive rehabilitation therapy program; (4) required physician supervision by a rehabilitation physician; and (5) required an intensive and coordinated interdisciplinary approach to providing rehabilitation (Pub. No. 100-02, chapter 1, § 110.2).

Furthermore, the *Medicare Benefit Policy Manual* states that a primary distinction between the IRF environment and other rehabilitation settings is the intensity of rehabilitation therapy services provided in an IRF. For this reason, the information in the patient’s IRF medical record must document a reasonable expectation that, at the time of admission to the IRF, the patient generally required the intensive rehabilitation therapy services that are uniquely provided in IRFs (Pub. No. 100-02, chapter 1, § 110.2.2).

⁴ 42 CFR § 412.622(a)(3), as interpreted in the *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 1, §§ 110.2 and 110.3.

⁵ 42 CFR §§ 412.622(a)(4) and (5), as interpreted in the *Medicare Benefit Policy Manual*, Pub. No. 100-02, chapter 1, §§ 110.1, 110.2.4, and 110.2.5.

⁶ These requirements apply equally to all Medicare patients regardless of whether the patient is treated in the IRF for 1 or more of the 13 medical conditions listed in 42 CFR § 412.29(b)(2) and used by Medicare for classifying a hospital or unit of a hospital as an IRF.

For 63 of the 165 sampled inpatient claims, the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for the higher acute inpatient rehabilitation level of care. The Hospital did not provide a cause for the errors because it continues to believe that these claims met Medicare requirements.

As a result of these errors, the Hospital received overpayments totaling \$1,126,690.

Incorrectly Billed Diagnosis-Related-Group Codes

The Act precludes payment to any provider without information necessary to determine the amount due the provider (§ 1815(a)). In addition, the Manual states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 23 of the 165 sampled inpatient claims, the Hospital billed Medicare with incorrect DRG codes that resulted in either higher or lower payments than should have been made. For these claims, the Hospital used incorrect diagnosis codes to determine the DRG codes. The Hospital attributed the errors to partially outdated Clinical Documentation Handbooks, which coders relied upon when coding these claims.

As a result of these errors, the Hospital received net overpayments of \$140,068.

OVERALL ESTIMATE OF OVERPAYMENTS

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$22,051,602 for the audit period.

RECOMMENDATIONS

We recommend that the Hospital:

- refund to the Medicare contractor \$22,051,602 (of which \$1,266,758 was net overpayments identified in our sample) in estimated overpayments for incorrectly billed services;⁷

⁷ OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeals. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

- exercise reasonable diligence to identify and return any additional similar overpayments received 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 controls to ensure full compliance with Medicare requirements.

COMMUNITY HOSPITAL COMMENTS

In written comments on our draft report, the Hospital generally disagreed with our findings and recommendations. The Hospital agreed that for some claims in the sample, the documentation supports a different level of reimbursement. The Hospital believed that the OIG had no apparent reason to select them for audit, disagreed with all of the findings on the inpatient rehabilitation claims reviewed and believed that we applied the wrong standards, and stated that OIG's sampling methodology was flawed and our use of extrapolation was inappropriate and premature.

The Hospital's comments are included in their entirety as Appendix E.⁸

OFFICE OF INSPECTOR GENERAL RESPONSE

After review and consideration of the Hospital's comments, we maintain that all of our findings and the associated recommendations are valid. This review is part of a series of hospital compliance reviews. For selecting hospitals for review, we employ a risk-based approach that uses computer matching, data mining, and various other data analysis techniques to identify hospital claims that are at most risk for noncompliance with Medicare billing requirements.

We conducted this audit in accordance with generally accepted government auditing standards, which requires that the audit be planned and performed so as to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions. We relied on the statutes and regulations, as well as CMS manual provisions interpreting those authorities, in existence at the time of the claims period under review. In each of our hospital compliance audits, we work closely with CMS, our legal counsel, and others within HHS to ensure that our understanding and application of the criteria is accurate.

We submitted the claims selected for review to an independent medical review contractor who reviewed the medical record in its entirety to determine whether the services were medically necessary and provided in accordance with Medicare coverage and documentation requirements. We worked with the medical reviewers to ensure that they applied the correct Medicare criteria and that they used professionals with appropriate medical expertise,

⁸ Community Hospital also included several appendices to its comments to our draft report. These appendices included claim-by-claim rebuttals to the findings in our draft report. However, this information contained protected health information so we excluded it for inclusion in this report.

including physicians with training and expertise in rehabilitation. We appropriately assessed the medical record documentation to determine if it supported a payment being made by Medicare. Services must be appropriately documented and Medicare must have the ability on a post-payment basis to verify that a payment was made in accordance with program requirements. For these reasons and because the Hospital's response to our draft report provided no new medical record documentation, a re-review was not warranted.

Regarding the Hospital's comments on our statistical sampling and extrapolation methodology, we note that the use of statistical sampling to determine overpayment amounts in Medicare is well established and has repeatedly been upheld on administrative appeal within the Department and in Federal courts.⁹ As described in Appendix B, our use of sampling and extrapolation was based upon a statistically valid methodology.¹⁰ We defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical sampling software to apply the correct formulas for the extrapolation. These formulas fully accounted for the stratified nature of the sampling design. The statistical lower limit that we use for our recommended recovery represents a conservative estimate of the overpayment that we would have identified if we had reviewed of each and every claim in the sampling frame. The conservative nature of this approach is not affected by the type of errors identified in this audit. We shared the results and methods for arriving at our estimates with the Hospital so that it can replicate the results.

The Hospital contends that our sample is not valid because we excluded certain code types when selecting the claims to include in our sampling frame. We appropriately used computer matching and data analysis techniques to focus our review on claims potentially at risk for noncompliance to include in our sampling frame and exclude other claims we considered low risk. Our overpayment estimate does not extend beyond the specific claims listed in our sampling frame. Finally, the Hospital's argument that our extrapolation was inappropriate because our error rate did not support a sustained or high level of payment error, according to guidelines prescribed for CMS and its contractors, is not applicable because OIG is not a Medicare contractor.¹¹

OIG audit recommendations do not represent final determinations by the Medicare program but are recommendations to HHS action officials. Action officials at CMS, acting through a MAC

⁹ See *Yorktown Med. Lab., Inc. v. Perales*, 948 F.2d 84 (2d Cir. 1991); *Illinois Physicians Union v. Miller*, 675 F.2d 151 (7th Cir. 1982); *Momentum EMS, Inc. v. Sebelius*, 2013 U.S. Dist. LEXIS 183591 at *26-28 (S.D. Tex. 2013), *adopted by* 2014 U.S. Dist. LEXIS 4474 (S.D. Tex. 2014); *Anghel v. Sebelius*, 912 F. Supp. 2d 4 (E.D.N.Y. 2012); *Miniet v. Sebelius*, 2012 U.S. Dist. LEXIS 99517 (S.D. Fla. 2012); *Bend v. Sebelius*, 2010 U.S. Dist. LEXIS 127673 (C.D. Cal. 2010).

¹⁰ See *John Balko & Assoc. v. Sebelius*, 2012 WL 6738246 at *12 (W.D. Pa. 2012), *aff'd* 555 F. App'x 188 (3d Cir. 2014); *Maxmed Healthcare, Inc. v. Burwell*, 152 F. Supp. 3d 619, 634-37 (W.D. Tex. 2016), *aff'd*, 860 F.3d 335 (5th Cir. 2017); *Anghel v. Sebelius*, 912 F. Supp. 2d 4, 18 (E.D.N.Y. 2012); *Transyd Enters., LLC v. Sebelius*, 2012 U.S. Dist. LEXIS 42491 at *13 (S.D. Tex. 2012).

¹¹ The Act § 1893(f)(3); CMS *Medicare Program Integrity Manual*, chapter 8.4.1.4 (effective June 28, 2011).

or other contractor, will determine whether a potential overpayment exists and will recoup any overpayments consistent with its policies and procedures. If a disallowance is taken, providers have the right to appeal the determination that a payment for a claim was improper (42 CFR § 405.904(a)(2)). The Medicare Part A/B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a hearing before an Administrative Law Judge. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$40,553,848 in Medicare payments to the Hospital for 2,510 claims that were potentially at risk for billing errors. These claims consisted of inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period. We selected a stratified random sample of 170 claims with payments totaling \$2,824,623 for review. These 170 claims had dates of service in CY 2015 or CY 2016 and consisted of 165 inpatient and 5 outpatient claims.

We focused our review on the risk areas that we had identified as a result of prior OIG reviews at other hospitals. We evaluated compliance with selected billing requirements and submitted 120 claims to an independent medical review contractor to determine whether the services met medical necessity and coding requirements.

We limited our review of the Hospital's internal controls to those applicable to the inpatient and outpatient areas of review because our objective did not require an understanding of all internal controls over the submission and processing of claims. We established 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.

This report focuses on selected risk areas and does not represent an overall assessment of all claims submitted by the Hospital for Medicare reimbursement.

We conducted our fieldwork from July 2017 through August 2018.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient and outpatient paid claim data from CMS's National Claims History file for the audit period;
- used computer matching, data mining, and analysis techniques to identify claims potentially at risk for noncompliance with selected Medicare billing requirements;
- selected a stratified random sample of 170 claims (165 inpatient and 5 outpatient) totaling \$2,824,623 for detailed review (Appendix B);
- reviewed available data from CMS's Common Working File for the sampled claims to determine whether the claims had been cancelled or adjusted;

- reviewed the itemized bills and medical record documentation provided by the Hospital to support the sampled claims;
- requested that the Hospital conduct its own review of the sampled claims to determine whether the services were billed correctly;
- reviewed the Hospital's procedures for submitting Medicare claims;
- used an independent medical review contractor to determine whether 120 sampled claims met medical necessity and coding requirements;
- discussed the incorrectly billed claims with Hospital personnel to determine the underlying causes of noncompliance with Medicare requirements;
- calculated the correct payments for those claims requiring adjustments;
- used the results of the sample review to calculate the estimated Medicare overpayments to the Hospital (Appendix C); and
- discussed the results of our review with Hospital officials.

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: SAMPLE DESIGN AND METHODOLOGY

TARGET POPULATION

The target population contained inpatient and outpatient claims paid to the Hospital for services provided to Medicare beneficiaries during the audit period.

SAMPLE FRAME

Medicare paid the Hospital approximately \$275 million for 19,098 inpatient and 169,827 outpatient claims for services provided to beneficiaries during the audit period based on CMS's National Claims History data.

We downloaded claims from the National Claims History database totaling \$190,199,999 for 10,351 inpatient and 37,417 outpatient claims in 24 risk areas. From these 24 risk areas, we selected 6, consisting of 8,988 claims totaling \$126,264,706 for further review.

We performed data analysis of the claims within each of the six risk areas. The specific data filtering and analysis steps performed varied depending on the risk area and Medicare issue, but included such procedures as removing:

- \$0 paid claims,
- claims with certain patient discharge status codes,
- claims with specific diagnosis and HCPCS codes,
- claims with payment amounts less than \$3,000 for risk areas one through three, and
- claims under review by the Recovery Audit Contractor as of May 1, 2017.

We assigned each claim that appeared in multiple risk areas to just one area on the basis of the following hierarchy: Inpatient Rehabilitation, Inpatient Claims Billed with High-Severity-Level DRG Codes, Inpatient Hospital-Acquired Conditions and Present on Admission Indicator, Inpatient Claims paid in Excess of Charges, and Inpatient Medical Device Credits. This assignment hierarchy resulted in a sample frame of 2,510 unique Medicare paid claims in 6 risk areas totaling \$40,553,848 (Table 1).

Table 1: Risk Areas Sampled

Risk Area	Number of Claims	Amount of Payments
Inpatient Rehabilitation Facility	1,911	\$34,424,890
Inpatient Claims Billed with High-Severity-Level DRG Codes	400	3,721,741
Inpatient Hospital-Acquired Conditions and Present on Admission Indicator Reporting	179	1,963,292
Inpatient Claims paid in Excess of Charges	1	33,689
Inpatient Medical Device Credits	14	302,080
Outpatient Medical Device Credits	5	108,156
Total	2,510	\$40,553,848

SAMPLE UNIT

The sample unit was a Medicare paid claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into six strata based on the risk area.

SAMPLE SIZE

We selected 170 claims for review, as follows:

Table 2: Sampled Claims by Stratum

Stratum	Risk Area	Claims in Sampling Frame	Claims in Sample
1	Inpatient Rehabilitation Facility	1,911	90
2	Inpatient Claims Billed With High-Severity-Level DRG Codes	400	30
3	Inpatient Hospital-Acquired Conditions and Present on Admission Indicator Reporting	179	30
4	Inpatient Claims Paid in Excess of Charges	1	1
5	Inpatient Medical Device Credits	14	14
6	Outpatient Medical Device Credits	5	5
	Total	2,510	170

SOURCE OF RANDOM NUMBERS

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

METHOD FOR SELECTING SAMPLE UNITS

We consecutively numbered the claims within strata one through three. After generating the random numbers for these strata, we selected the corresponding frame items. We selected all claims in strata four through six.

ESTIMATION METHODOLOGY

We used the OIG/OAS statistical software to estimate the total amount of overpayments paid to the Hospital during the audit period. To be conservative, we recommend recovery of any 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 95 percent of the time.

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

Table 3: Sample Results

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Total Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Over-payments in Sample
1	1,911	\$34,424,890	90	\$1,663,901	63	\$1,126,690
2	400	3,721,741	30	366,288	12	59,985
3	179	1,963,292	30	350,509	10	54,437
4	1	33,689	1	33,689	1	25,646
5	14	302,080	14	302,080	0	0
6	5	108,156	5	108,156	0	0
Total	2,510	\$40,553,848	170	\$2,824,623	86	\$1,266,758

**Table 4: Estimates of Overpayments for the Audit Period
(Limits Calculated for a 90-Percent Confidence Interval)**

Point estimate	\$25,073,643
Lower limit	\$22,051,602
Upper limit	\$28,095,683

APPENDIX D: RESULTS OF REVIEW BY RISK AREA

Table 5: Sample Results by Risk Area

Risk Area	Sampled Claims	Value of Sampled Claims	Claims With Over-payments	Value of Over-payments
Inpatient				
Inpatient Rehabilitation Facility	90*	\$1,663,901	63	\$1,126,690
Claims Billed With High-Severity-Level DRG Codes	30*	366,288	12	59,985
Inpatient Hospital-Acquired Conditions and Present on Admission Indicator Reporting	30	350,509	10	54,437
Inpatient Claims Paid in Excess of Charges	1	33,689	1	25,646
Inpatient Medical Device Credits	14	302,080	0	0
Inpatient Totals	165	\$2,716,467	86	\$1,266,758
Outpatient				
Outpatient Medical Device Credits	5	\$108,156	0	\$0
Outpatient Totals	5	\$108,156	0	\$0
Inpatient and Outpatient Totals	170	\$2,824,623	86	\$1,266,758

* We submitted these claims for an independent medical review to determine whether the services met medical necessity and coding requirements.

Notice: The table above illustrates the results of our review by risk area. In it, we have organized inpatient and outpatient claims by the risk areas we reviewed. However, we have organized this report's findings by the types of billing errors we found at the Hospital. Because we have organized the information differently, the information in the individual risk areas in this table does not match precisely with this report's findings.

APPENDIX E: COMMUNITY HOSPITAL COMMENTS



December 14, 2018

VIA FEDEX AND ELECTRONIC MAIL

Sheri L. Fulcher
Regional Inspector General for Audit Services
Office of Audit Services, Region V
233 North Michigan, Suite 1360
Chicago, IL 60601

**RE: Community Hospital Response to OIG Draft Report Number:
A-05-17-00026**

Dear Ms. Fulcher:

Community Hospital (“Community”) appreciates the opportunity to provide comments on the U.S. Department of Health and Human Services, Office of the Inspector General’s (“OIG’s”) draft report entitled *Medicare Compliance Review of Community Hospital* (“the Draft Report”). Community is committed to complying with all statutes, regulations, and other standards governing participation in federal health care programs, including Medicare, and intends to maintain and improve its internal controls and monitoring processes to minimize the risk of errors.

Community strongly disagrees with most of OIG’s conclusions and recommendations. OIG conducted a stratified sample of 170 inpatient and outpatient claims from calendar years (“CYs”) 2015 and 2016 and alleged that Community did not fully comply with Medicare billing requirements for 86 inpatient claims, resulting in net overpayments of \$1,266,758. OIG used the determination to calculate an extrapolated overpayment of \$22 million and recommended that Community use reasonable diligence to identify and return any additional similar overpayments outside the OIG audit period and strengthen its controls to ensure full compliance with Medicare

I. Executive Summary

Community disputes the vast majority of OIG's findings. As an initial matter, OIG had no apparent reason to select Community for audit. OIG has offered explanations for the audit that do not square with the facts. Community's IRF has been audited several times recently by Medicare contractors, and those results have been largely favorable to Community. OIG claims that Community's Program for Evaluating Payment Patterns Electronic Report ("PEPPER") showed a deviation from its peers, but Community's PEPPER Report is not at all aberrant in the areas audited by OIG.

Community disagrees with OIG's assertion that 63 of 90 IRF claims were not payable. Community has a rigorous process for admitting IRF patients. Community's medical director stands behind these admissions, and Community also retained an independent medical expert, Dr. Karl Sandin, to analyze the records. Dr. Sandin concluded that 51 of the patients definitely met Medicare coverage requirements, and the admitting physician could reasonably have determined that the other 12 met Medicare requirements. Dr. Sandin also expressed concerns with the quality of OIG's review given that the findings show a basic lack of understanding of rehabilitation medicine.

OIG also applied the wrong standards to the IRF claims. OIG relied primarily upon the Medicare Benefit Policy Manual ("MBPM"), which is non-binding guidance. The MBPM was not issued using notice and comment rulemaking as required under the Medicare statute and the Administrative Procedure Act ("APA"). Federal courts and the Attorney General have both concluded that guidance does not have the force of law. OIG therefore erred when denying IRF claims that allegedly did not meet standards in the MBPM that are not also clearly stated in regulations.

Therefore, OIG should re-audit the claims, using a different reviewer who is a physician that is board certified in physical medicine and rehabilitation and has training and experience in IRF care, and OIG should apply the IRF coverage regulation, not the MBPM. OIG's auditor should recognize that a paper review cannot replicate an in-person examination by a treating physician, and the auditor should, therefore, defer to the treating physician's admission decision unless that decision is clearly contradicted in the record.

We have brought many of these concerns to OIG's attention during the audit and afterwards, but OIG has not changed any of its preliminary conclusions. OIG has repeatedly failed to address Community's detailed responses and issued a Draft Report with language virtually identical to that included in its initial Objective Attributes Recap Sheet. OIG has not

reexamined any of the claim determinations, despite Community presenting analysis and evidence from a board certified psychiatrist with extensive experience in IRF care, contradicting the findings of OIG's medical reviewer. This latter oversight, if continued through publication of OIG's final audit report, will force Community to appeal all of the unfavorable claim determinations through the multi-year backlogged Medicare appeals process.

OIG's audit of Community's DRG coding was higher quality. Community agrees with OIG's determinations in all but three cases. Community intends to appeal these three if they are ultimately denied. Community has implemented new procedures to ensure that it codes claims correctly in the future.

Community also objects to OIG's sampling and extrapolation methodology. Community retained a statistician, Dr. George McCabe, who determined that OIG's sample is not representative of the universe of claims. Indeed, OIG admits to removing certain claims from the sample. OIG appears to have "cherry picked" the claims, rendering the sample non-random. The result is an overpayment demand of \$22 million, a stunning figure that assumes that Community Hospital will not prevail at the Administrative Law Judge ("ALJ") level on even one of the 63 IRF claims and exposes the government to an equally stunning liability for underpayments with interest, which are certain to occur when Community Hospital prevails on a many, if not all, of the claims at the ALJ level. Thus, OIG should recommend recoupment of only the claims that it actually reviewed, and an extrapolated demand should not be imposed.

Because OIG's audit is so fundamentally flawed, there is no basis for its recommendations. Community disagrees that it should refund \$22,051,602 because that figure is based on flawed sampling and incorrect IRF claim determinations. Community has already repaid 20 DRG coding errors for a total of \$122,827.12. Community also disagrees that it must conduct additional audits of IRF claims because all claims reviewed by OIG are in fact payable. Finally, Community largely disagrees that it should strengthen its internal controls. Community's current process for admitting IRF patients, however, is rigorous and ensures that all patients meet Medicare coverage requirements. However, if OIG can recommend specific process improvements, we would be happy to consider them. Community has already implemented additional procedures to prevent future DRG coding errors.

II. Background of Audit and Community's Work With OIG

On June 21, 2017, Community received OIG's Initial Documentation Request. Over the following months, Community worked with OIG to submit all requested documentation and provide additional requested information. On March 5, 2018, Community received the initial results of OIG's audit, alleging errors in 86 of the 170 claims reviewed. At this time, Community was asked by OIG to complete an Internal Controls Questionnaire ("ICQ").

Community submitted the completed ICQ to OIG on March 23, 2018. In its ICQ response, Community strongly disputed the IRF findings and explained in detail its internal controls, including its admission procedures and its compliance monitoring practices. (Community does not dispute many of the DRG coding findings, as explained in greater detail below.)

On May 1, 2018, OIG issued its Objective Attributes Recap Sheet (“Recap”). OIG did not respond to Community’s detailed ICQ submission. Instead, OIG asked for a proposed timeframe to schedule an exit conference at Community and permitted Community to respond to the Recap. Prior to the exit conference, Community submitted an extensive written response to the Recap, including a report from an independent medical expert refuting OIG’s claim determinations. The exit conference was held on August 1, 2018. OIG informed Community that it would not discuss any specific findings during the exit conference.

Community expected that OIG would consider Community’s submission prior to issuing the Draft Report, but OIG apparently did not, as it did not alter its findings or respond to Community’s objections. OIG conceded that it does not have the expertise to assess the medical necessity and appropriate coding of Medicare claims and must instead rely upon contractors. OIG was very clear at the exit conference that it would not reengage its medical review contractor to address the disputed claims prior to issuing the Draft Report. In fact, OIG went so far as to state that it would not commit to reengage the medical reviewer to examine Community’s claim-by-claim analysis submitted with its response to the Draft Report.

Given the multi-year backlog at the ALJ level of appeal, OIG’s failure to correct its erroneous denials now would deny payment for medically necessary claims for years. Therefore, OIG should engage a new physician reviewer that is board certified in physical medicine and rehabilitation and has training and experience in IRF care to reevaluate the individual claims and consider the arguments and evidence submitted by Community previously and with this Response.

Moreover, due to the current appeals backlog, extrapolation exposes the government to an enormous liability for interest that will be owed to Community if it prevails, as it expects to do, on the majority of the appeals at the ALJ level. If Community prevails at the ALJ level at the industry average of 87%, the liability to Community at the current interest rate on underpayments of 10.625% would be \$26.2M after three years and \$32.1M after five years. It is short-sighted for the OIG to overlook the ramifications to taxpayers for the inappropriate use of extrapolation.

III. The Selection of Community for Audit Is Based on Flawed Factors

Community cannot understand why the OIG subjected it to this audit. In fact, Community has already been subjected to audits of this time period, with largely favorable results. In 2016, the Supplemental Medical Review Contractor (“SMRC”) reviewed 40 IRF claims from 2014 and 2015. After 21 claims were initially denied, all but one was overturned during the rebuttal phase, resulting in successful payment determinations in 97.5% of the audited claims.¹

In a subsequent post-payment review conducted by the Medicare Administrative Contractor (“MAC”), another 40 claims from 2015 and 2016 were audited. While 32 claims were initially denied, 11 were overturned on appeal. The remaining 21 claims remain pending at the ALJ level of appeal, and Community expects that these denials will be overturned.² Following the post-payment review of 40 claims, the MAC undertook additional post- and pre-payment reviews covering claims with dates of service in 2015 and 2016. Community believes the MAC was further testing its compliance with coverage criteria through these audits. In the subsequent audits of IRF claims, 123 claims were audited, with 92 claims initially paid. Furthermore, an additional seven claims were paid following appeal, and 26 are pending at the ALJ level. At the current level of payment, Community’s compliance percentage for the subsequent audits was 83.7%, and Community expects to be successful in the majority of the remaining appeals as well.³ Community’s past performance on these audits demonstrates a high level of compliance, including marked improvement in follow-up audits after a less favorable review. Given this level of compliance and the duplicative nature of further reviews of the same time period, Community’s IRF services did not warrant OIG’s review.

Even in the absence of prior, duplicative audits, it is unclear why OIG selected Community for review. In the Draft Report, OIG stated that it used “computer matching, data mining, and other data analysis techniques” to select Community. At the exit conference, OIG suggested that Community’s PEPPER Report was part of this analysis. However, Community’s PEPPER reports for the applicable time periods show little to no deviation from the hospital’s historical patterns. Furthermore, while the PEPPER Reports did show some deviation from Community’s peers in several areas (i.e., emergency department evaluation and management visits, chronic obstructive pulmonary disease claims, and 30-day readmissions), these areas do not correlate to the claims actually audited by OIG. Combined with its general conformance

¹ The single remaining denial was based upon an isolated technical deficiency in documentation, not medical necessity criteria.

² To date, Community has never had an appeal related to IRF services heard before an ALJ. However, across the service sector, IRFs earn favorable decisions from ALJs in 87% of their appeals. Brief for the Fund for Access to Inpatient Rehabilitation as Amicus Curiae, p. 3, *Am. Hosp. Ass’n v. Azar*, Case No. 1:14-cv-00851-JEB (D.C. Cir. June 21, 2016). Based on these statistics and Community’s robust admissions process, Community believes it will have a similar (or higher) rate of favorable determinations.

³ See *supra* note 2.

with its peers, as shown on the PEPPER reports, Community should not have been subjected to audit by OIG.

Regardless of the OIG's reason for selecting Community Hospital for audit, extrapolation is inappropriate because, except in cases where fraud is alleged or suspected, extrapolation is reserved for situations where a probe audit determines a high error rate or audits of different time periods find a sustained error rate. The OIG did not conduct a probe audit and the only claims that have been audited repeatedly are claims from 2015 and 2016.

The SMRC audit of 40 claims from this period ultimately disallowed only one claim on technical grounds. The MAC audit of 40 claims from this period questioned the medical necessity of 32 claims, 11 of which the MAC or QIO has already found were medically necessary. The remaining 21 are awaiting an ALJ hearing and should not be included in the numerator for calculating an error rate until the ALJ decision is rendered.

The MAC's subsequent pre-payment and post-payment review of an additional 123 claims from 2016 has found 80% of those claims were medically necessary and the remaining 26 are pending an ALJ hearing and likewise should not be included in the numerator for purposes of calculating an error rate until an ALJ decision is rendered.

In summary, of Community's 203 IRF claims reviewed for medical necessity by the SMRC and the MAC for the period 2014-2016, 149 of those claims (73%) have already been found to be medically necessary. The remaining 47 are awaiting an ALJ hearing, where 87% of disputed IRF medical necessity determinations are resolved in favor of the IRF, which could reduce the ultimate error rate to approximately 6%. Accordingly, extrapolation is contrary to long-standing Medicare policy on appropriate use of extrapolation because it has not been established that there is either a high error rate or a sustained error rate sufficient to justify use of extrapolation by the OIG.

IV. OIG's Audit of IRF Services Is Flawed and Should Be Performed Again

OIG applied the wrong standards in auditing the IRF claims. OIG's reviewer demonstrates a lack of understanding of rehabilitation medicine and improperly denied 63 claims. Community and its medical staff stand behind these admissions; in fact, it is notable that all of the patients treated in the IRF returned to the community—a highly commendable achievement. OIG also denied claims that allegedly did not comply with non-binding guidance. OIG should instead have applied the IRF coverage regulation. OIG should re-audit the IRF claims, using a different auditor who is a physician who is board certified in physiatry and has experience in rehabilitation medicine. OIG should apply the correct coverage standards and afford a more appropriate level of deference to the treating physicians' admission decisions.

A. OIG's Denials Are In Error and Should Be Reversed

Community complies with the coverage criteria established by the Centers for Medicare and Medicaid Services ("CMS") for IRF services. Community employs a comprehensive preadmission screening process to ensure that all IRF admissions meet Medicare coverage requirements. Community complies with the federal regulation that requires that, at the time of admission, there is a reasonable expectation that the patient meets all of the following requirements: (1) the patient requires the active and ongoing intervention of multiple therapies, including physical or occupational therapy; (2) the patient is sufficiently stable and able to participate actively in and demonstrate measurable functional improvement in an intensive rehabilitation therapy program; and (3) the patient requires supervision by a rehabilitation physician to assess the patient medically and functionally and to modify the course of treatment to maximize the patient's capacity to benefit from the rehabilitation process.⁴ Further, the OIG review confirms that Community consistently completes all documentation required by 42 C.F.R. § 412.622. Community's documentation addresses each patient's ongoing need for physician supervision and efforts to address medical complexities.

Community employs a three-tiered comprehensive preadmission screening process for all patients considered for admission to its IRF, including the patients audited by OIG. When a patient is referred for admission to Community's IRF, its Clinical Liaison and the Medical Director review the patient's medical record to assess whether an IRF stay is medically necessary and whether the Medicare IRF admission criteria are met. If the patient's need for IRF care cannot be determined from the medical record alone, a Community rehabilitation physician examines the patient at the acute care hospital to ensure that the patient meets the requirements for an IRF admission. Once the initial review is completed, the Clinical Liaison prepares the Pre-Admission Screening ("PAS"), which is then reviewed by the Program Director, an administrator for the IRF. The completed PAS is examined by a rehabilitation physician who must concur with the findings of the preadmission assessment that the patient meets Medicare criteria for an IRF admission. The rehabilitation physicians who review these preadmission screenings are experts in rehabilitation medicine with lengthy experience, 18 and 22 years respectively. Both are certified in Physical Medicine and Rehabilitation by the American Board of Physical Medicine and Rehabilitation. The Clinical Liaisons who complete the preadmission screenings receive comprehensive training when they are hired and regular ongoing education about CMS regulations and requirements for completing the preadmission screening.

This review results in Community declining to admit 54% of patients. In 2017, that percentage increased to 65%. These numbers are significant, with more than half of all referrals

⁴ 42 C.F.R. § 412.622(a)(3).

made to Community's IRF rejected under the preadmission screening process. These figures help demonstrate that Community's safeguards are serving to ensure that only appropriate patients are admitted to the IRF.

Despite this rigorous process, OIG's medical reviewer nonetheless determined that 63 of 90 IRF claims were inappropriate for reimbursement. OIG's denials are wrong. Community's Medical Director for its IRF, Dr. Padmaja Neelaveni stands by the admissions.⁵ (See Appendix 1, paragraphs 10-11.) Dr. Neelaveni was either the admitting and treating physician for the admitted patients or had an integral role as Medical Director in approving the admissions. Community has reviewed the medical records and prepared case summaries of each unfavorable determination. Dr. Neelaveni has reviewed the summaries and attests that they accurately reflect the admission and care for each patient. (See Appendix 1, paragraph 11; Appendix 2.⁶) She fully supports Community's decision to oppose OIG's findings and appeal any unfavorable determinations.

Furthermore, Community retained an independent medical expert to review the claims determined to be in error in the Draft Report. Dr. Karl Sandin, a board-certified physical medicine and rehabilitation physician with extensive experience in admission and documentation standards for IRFs, reviewed each of the 63 claims and determined that he personally would have admitted all but 12 of the patients. (See Appendices 3 and 4.) For the remaining 12 patients, Dr. Sandin concluded that, based on the facts documented in the medical records, a rehabilitation physician with direct contact with the patient could have reasonably admitted the patient. Dr. Sandin also prepared full analyses of each of the 51 patients he would have admitted personally.

Appendix 4 contains all of Dr. Sandin's analyses.⁷ Two examples highlight OIG's errors. The patient in OIG Sample A-41 was an elderly woman admitted to a general acute care hospital and was diagnosed with tachycardia and pneumonia. She was treated with several antibiotics, and her treatment was complicated by cellulitis and gangrene in her leg. She had a prior above-the-knee amputation of the other leg. She also suffered from chronic obstructive pulmonary disease, and peripheral arterial disease. Prior to hospitalization, she used a wheelchair most of the time because of her amputation, but she did some walking at a modified independent level with the prosthesis.

⁵ Dr. Neelaveni refers to the IRF as an acute rehabilitation unit ("ARU").

⁶ Appendix 2 contains summaries of the medical records for 63 of Community's patients. As such it may contain protected health information ("PHI") and should be omitted from the final published report to be issued by OIG.

⁷ Appendix 4 contains summaries of the medical records for 51 of Community's patients. As such it may contain PHI and should be omitted from the final published report to be issued by OIG.

When Community's IRF examined her, she had to be supervised when moving in bed and required another person to perform 50% of the effort to transfer her from bed to a wheelchair. Her rehabilitation was complicated by anxiety, which required extensive work pharmacologically and with the interdisciplinary team to keep her focused on rehabilitation therapy. She was quite sick and required thoracentesis. She was seen by multiple medical specialties including podiatry, infectious disease, internal medicine, pulmonology, and psychiatry.

This patient suffered from substantial impairments and limitations in her activities. Dr. Sandin concluded that, at admission, the patient was likely to make measurable, practical improvements within a prescribed period of time; was stable to participate in and benefit from an intensive rehabilitation program; had comorbidities that reasonably could affect the rehabilitation process and thus required physician supervision to mitigate adverse effects of those comorbidities in rehabilitation; and had risks for complications during rehabilitation that also required physician supervision.

OIG's reviewer asserted that there was no new injury or significant impairing condition to support the IRF admission. Dr. Sandin disagrees. Prior to coming to the IRF, the patient was quite ill for enough time to develop the etiologic diagnosis of debility, impairment group code 16. OIG's reviewer falsely asserted that a primary rehabilitation diagnosis of debility does not support the medical necessity of IRF care. Dr. Sandin points out that debility is one of the qualifying impairment group codes for inpatient rehabilitation.

OIG's reviewer also claimed that this patient was a high risk for further limb loss and was unable to safely participate in the required intensity of the IRF therapy program. Dr. Sandin states that there is no evidence in the record that the patient's ischemic limb was fragile. There is also no evidence that the patient missed therapy or had therapy canceled because she was unable to participate safely. Thus, the reviewer's claim that the patient could not participate in intensive therapy is plainly refuted by the patient's actual participation in intensive therapy.

OIG's reviewer went on to state that the complexity of the patient's nursing, medical management, and rehabilitation needs did not require an inpatient stay and an interdisciplinary team approach. Dr. Sandin disagrees, noting that this patient was able to progress to a modified independent level of mobility, transfers, and full body dressing despite her anxiety and her non-weight-bearing status on her left lower leg. This complicated care indicates the success of interdisciplinary treatment.

OIG's reviewer found no clear need for occupational therapy. Dr. Sandin disagrees because, upon admission to the IRF, the record shows that the patient had deficits in self-care, which is one of the purposes of occupational therapy. Dr. Sandin concluded that an intensive rehabilitation therapy program beneficially impacted her condition and was demonstrably

superior to therapy at a less intense level. Her inpatient rehabilitation was medically necessary and justified.

OIG's findings in sample A-87 were equally erroneous. This was an octogenarian who came to the emergency department with congestive heart failure and anemia due bleeding from ulcers. She also had pneumonia. When she was transferred to Community's IRF, she was incapable of dressing her lower body, required 25% assistance to move within the bed, 50% assistance to move from bed to a wheelchair, and 25% assistance to walk for only 20 feet. She was seen by multiple physician specialists in the IRF including gastroenterology, hematology, pulmonology, cardiology, nephrology, hospital medicine, and psychiatry.

Dr. Sandin concluded that this patient was likely to make measurable, practical improvement and was stable enough to participate in and benefit from intensive rehabilitation. Dr. Sandin states that the patient had comorbidities and risks of complications that reasonably could affect the rehabilitation process and required physician supervision to mitigate adverse effects of those comorbidities in rehabilitation.

OIG's reviewer claims that the patient had a primary rehabilitation diagnosis of debility and asserted, once again, that a debility diagnosis does not support the medical necessity of IRF care. Dr. Sandin disagreed that the primary diagnosis was debility and agreed with Community's classification of the patient with impairment group code 9, cardiac. Dr. Sandin concluded that the OIG reviewer's erroneous diagnosis led to incorrect conclusions about the medical necessity of IRF care. The OIG reviewer also asserted that the complexity of the patient's nursing, medical management, and rehabilitation needs did not require an inpatient stay and an interdisciplinary team approach. Dr. Sandin disagrees, noting that the patient was seen by at least six different physician specialists in the IRF, and this intensity of medical management would only have occurred in an IRF.

OIG's reviewer also claimed that the patient had no clear need for occupational therapy because the reviewer believed that the patient's debility could be addressed with progressive mobilization through physical therapy. Again, debility was not the etiologic diagnosis. Moreover, Dr. Sandin points out that the patient had significant deficits in self-care, which is one of the focuses of occupational therapy. OIG's reviewer argued that the patient was limited by debility and the severity of her comorbid medical conditions and was not able to fully participate in or benefit from the IRF program. Again, the facts belie this claim because the patient did not cancel or miss any therapy sessions due to medical conditions.

Dr. Sandin concluded that IRF care significantly improved the patient's condition and was medically necessary. After the IRF stay, the patient was able to walk with an assistive device and was able to return home rather than to an institutional setting.

Dr. Sandin's review of the records left him with "serious concerns about the quality of the OIG's audit," the qualifications of the reviewer, the reviewer's understanding of rehabilitation diagnoses, the reviewer's apparent blanket rejection of patients with a diagnosis of debility, and the reviewer's basic understanding of the therapy services provided in an IRF:

In summary, the external reviewer's statements reflect a profound lack of understanding of the comprehensive nature of IRF services, and, in some cases, a lack of thoroughness in actually reviewing the patients' medical records. The reviewer's negative findings are not consistent with the facts of these cases, Medicare coverage rules, or established standards of medical practice.

Appendix 3.

Dr. Sandin's findings call into question the OIG's unsupported assertion as to the qualifications of its reviewers. OIG claims that the personnel involved in the review have the appropriate credentials and qualifications, but when asked to identify the reviewers and/or their credentials, the OIG has declined to do so.

B. OIG Improperly Denied Claims Based on Non-Binding Guidance

The Draft Report primarily cites chapter 1, section 110, of the MBPM, CMS Publication 100-02, as authority for the IRF coverage standards. Any standards in the MBPM that go beyond those stated in the regulation are not binding because the MBPM was not issued through notice and comment rulemaking as mandated by the APA, 5 U.S.C. § 553(b) and the Medicare statute, 42 U.S.C. § 1395hh(a)(2).⁸ Medicare manuals can explain the agency's interpretation of statutes or regulations but cannot impose binding requirements.⁹

Just last year, the D.C. Circuit held that "the Medicare Act requires notice-and-comment rulemaking for any (1) 'rule, requirement, or other statement of policy' that (2) 'establishes or changes' (3) a 'substantive legal standard' that (4) governs 'payment for services.'"¹⁰ These requirements also apply to guidance, such as the MBPM.¹¹ A federal district court recently held

⁸ *Allina Health Servs. v. Price*, 863 F.3d 937, 944 (D.C. Cir. 2017), *cert. granted*, No. 17-1484 (U.S. Sept. 27, 2018); *Cumberland Cty. Hosp. Sys. v. Price*, No. 5:15-cv-319-D, 2017 WL 1048102 (E.D.N.C. Mar. 1, 2017).

⁹ *See Allina Health Servs.*, 863 F.3d at 944; *see also Cumberland Cty. Hosp. Sys.*, No. 5:15-cv-319-D, 2017 WL 1048102.

¹⁰ *Allina Health Servs.*, 863 F.3d at 943 (quoting 42 U.S.C. § 1395hh(a)(2)).

¹¹ *See id.* at 944 ("Unlike the APA, the text of the Medicare Act does not exempt interpretive rules from notice-and-comment rulemaking.")

that the MBPM imposes substantive requirements on IRF claims that are not enforceable because the MBPM was not issued via notice-and-comment procedures.¹²

The Department of Justice (“DOJ”) has issued memorandums affirming that “guidance may not be used as a substitute for rulemaking and may not be used to impose new requirements on entities outside the Executive Branch.”¹³ DOJ issued a second memorandum applying these principles to enforcement actions.¹⁴ DOJ has articulated the proper role of agency guidance, and determined what impact that guidance may have on enforcement of federal law.

OIG’s reviewer did not identify the precise passages of chapter 1, section 110, of the MBPM that Community allegedly failed to satisfy, and we request that OIG provide us with this information. Guidance documents, such as the MBPM, cannot impose substantive requirements upon the regulated public unless those requirements are present in a statute or regulation. Where the MBPM imposes requirements that are not present in a statute or regulation, Medicare contractors, such as the one used by OIG, are not permitted to use the MBPM guidance to deny IRF claims.

C. OIG Should Re-review the Denied Claims Using a Qualified Rehabilitation Physician With Appropriate Deference to the Treating Physicians

As shown through the extensive attached summaries and the previously provided medical records, Community appropriately admitted and treated all 90 patients audited by OIG. Community urges OIG to engage a new medical reviewer to reassess the 63 claims that it asserts did not meet coverage requirements. This should be a reviewer who is board certified in physical medicine and rehabilitation and with experience in rehabilitation because CMS’s regulation is clear that only “a licensed physician with specialized training and experience in inpatient rehabilitation” is qualified to assess whether a patient requires IRF care.¹⁵ Also, consistent with the regulation, the reviewer should give appropriate deference to the physicians who actually examined and treated the patients.

It is critical that OIG assign a physician with training and experience in rehabilitation to review Community’s IRF claims. The coverage criteria established at 42 C.F.R. § 412.622 specify that only a rehabilitation physician may determine whether a patient is appropriate for admission to an IRF. This regulation puts the rehabilitation physician who actually examines and treats the patient in a role that is unique in Medicare. Under the regulation, IRF physician

¹² *Cumberland Cty. Hosp. Sys.*, 2017 WL 1048102, at *13.

¹³ Memorandum from Attorney Gen. Jefferson B. Sessions III to All Components, U.S. Dep’t of Justice 1 (Nov. 16, 2017) (available at <https://www.justice.gov/opa/press-release/file/1012271/download>) (“Sessions Memorandum”).

¹⁴ Memorandum from Assoc. Attorney Gen. Rachel Brand to Heads of Civil Litig. Components, U.S. Attorneys 2 (Jan. 25, 2018) (available at <https://www.justice.gov/file/1028756/download>) (“Brand Memorandum”).

¹⁵ 42 C.F.R. §§ 412.622(a)(3)(iv), (a)(4)(i)(D).

documentation is extensive and designed to ensure that the treating physician addresses all coverage requirements. This heightens the rehabilitation physician's role under the IRF regulations, and CMS itself has acknowledged that the treating physician is solely qualified to assess coverage.¹⁶ This important distinction warrants at least some deference to the treating physician.

Based on our review, it appears that the OIG's auditor failed to grant any deference to the physicians who actually treated Community's IRF patients. An auditor who examines only the paper record after the patient is discharged lacks the treating physician's more nuanced understanding of the patient's condition. Courts have long acknowledged that CMS should grant some additional weight to the treating physician's decision:

[W]e would expect the Secretary [of Health and Human Services] to place significant reliance on the informed opinion of a treating physician and either to apply the treating physician rule, with its component of "some extra weight" to be accorded to that opinion, or to supply a reasoned basis, in conformity with statutory purposes, for declining to do so.¹⁷

Other courts have concurred that the treating physician's opinion should be given "considerable deference" and "controlling weight" if it is "well-supported by medically accepted clinical and laboratory diagnostic techniques and is not inconsistent with . . . other substantial evidence."¹⁸

Although CMS issued a ruling in 1993 stating that, as a general rule, the Medicare program would not grant "presumptive weight" to a treating physician's conclusions, that ruling was issued nearly 20 years before the IRF coverage regulation. The 2010 IRF regulation established detailed coverage and documentation standards, and CMS was clear that the regulation places "more weight on the rehabilitation physician's decision to admit the patient to the IRF" than the previous coverage guidance.¹⁹ CMS emphasized the "unique training and experience of the rehabilitation physician, as he or she performs a hands-on evaluation of the patient."²⁰ CMS also stated its "belief that a rehabilitation physician is that professional who is uniquely qualified to assess all aspects of the patient's medical condition."²¹ The unique role of

¹⁶ Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2010, 74 Fed. Reg. 39,762, 39,791 (Aug. 7, 2009) [hereinafter IRF Final Rule Fiscal Year 2010].

¹⁷ *State of New York ex. rel. Holland v. Sullivan*, 927 F.2d 57, 60 (2d Cir. 1991).

¹⁸ *United Med. Healthcare v. Dep't of Health & Human Servs.*, 889 F. Supp. 2d 832, 844 (E.D. La. 2012); see also, *Exec. Director of the Office of Vt. Health Access ex. rel. Carey v. Sebelius*, 698 F. Supp. 2d 436, 441 (D. Vt. 2010) ("[C]ase law requires ALJs to give some extra weight to a treating physician's opinion, or supply a reasoned basis for declining to do so."); *Pfalzgraf v. Shalala*, 997 F. Supp. 360, 366 (W.D.N.Y. 1998); *Bergeron v. Shalala*, 855 F. Supp. 665, 668 (D. Vt. 1994); *Smith ex rel. McDonald v. Shalala*, 855 F. Supp. 658, 664 (D. Vt. 1994).

¹⁹ IRF Final Rule Fiscal Year 2010, 74 Fed. Reg. at 39,791.

²⁰ *Id.* at 39,792.

²¹ *Id.* at 39,796.

the treating rehabilitation physician in IRF care, as established in the regulation and CMS's comments to the IRF final rule, heightens the role of the rehabilitation physician, requiring deference to the treating physician's opinion.

V. OIG's Assessment of DRG Coding Issues

OIG also determined that 23 of the 170 sampled claims were billed with incorrect DRG codes, resulting in payments that were either too high or too low. Community concurs with OIG's findings in 20 of these DRG coding determinations. Community has already repaid the 20 claims for a total of \$122,827.12. However, Community disputes OIG's findings on the remaining three claims and intends to appeal if the MAC recoups the payments.

For OIG Audit Sample # B-20, Community maintains that the higher DRG code is in fact supported by the documentation in the medical record. OIG asserted that the claim should have been paid under DRG 667. Community's coders determined that the claim was actually under-coded because it should have been assigned to DRG 665, which has a higher Medical Severity ("MS") DRG weight.

For OIG Audit Sample # B-24, Community disagrees with the medical reviewer's determination that the secondary diagnosis of acute kidney injury was incorrect. Based on multiple instances of physician documentation of acute kidney injury throughout the medical record, Community maintains that the secondary diagnosis was correct.

Finally, for OIG Audit Sample # B-26, Community maintains that the treatment provided to the patient (i.e., intravenous Lasix) and the physician's response to a coding inquiry identifying the patient as having acute heart failure supports the selection of the DRG code for acute heart failure in addition to chronic heart failure ("Acute on chronic HF"). Therefore, Community disagrees with the medical reviewer's determination that the lower DRG of only chronic heart failure is more appropriate.

The coding errors for the 20 claims that OIG correctly disallowed resulted from Community's coders using outdated guidance. Community also identified some coding issues related to the use of external vendors. As we explained in our ICQ Response, Community has taken or will take the following steps to correct these issues:

- The Clinical Documentation Improvement ("CDI") Handbook will be purchased annually rather than biannually;
- A list of high risk DRG codes was compiled, and claims using codes on the list will trigger a second coding review prior to submission;

- Regularly scheduled coding discussions are now held at coding team meetings and at Community’s internal CDI “lunch & learn” sessions. These are also shared with outside coding vendors;
- Community will work with its outside coding vendor to correct inaccurate coding issues;
- CDI staff and training were increased; and
- Community will use specialized software to detect coding anomalies.

In addition, Community has audited and will continue to audit its coding periodically to ensure ongoing compliance with DRG coding rules for Medicare claims.

VI. OIG’s Use of Extrapolation to Estimate an Overpayment Amount of \$22 Million Is Inappropriate

Community strongly objects to OIG’s use of extrapolation. OIG estimates an overpayment of \$22,051,602—more than 17 times the actual amount of the individual claims that OIG alleges are overpayments. This amount is grossly excessive and imposes an unreasonable burden upon Community Hospital that may have dire consequences for its future operations. OIG’s sampling and extrapolation were fundamentally flawed and cannot, therefore, serve as the basis for such an estimated overpayment.

A. OIG’s Use of Extrapolation Is Premature

As a threshold consideration, the use of extrapolation is only appropriate where either a high level of payment error exists or documented educational intervention had failed to correct the payment errors.²² In its Draft Report, OIG does not determine or allege that an educational intervention has failed. Furthermore, it is premature to make a finding of a high payment error rate. Community believes that an independent re-review of the IRF claims determined to be improperly paid, if completed by a qualified physician with rehabilitation training and experience, will result in a significantly different outcome on the medical necessity determinations. In addition, as Community maintains that the claims were properly submitted and intends to appeal, based on the high rate of reversal usually experienced on appeal by IRFs (i.e., 87%), it is highly probable that the final payment error rate will be quite low.

This has significant implications for OIG’s extrapolation. For each claim that is ultimately determined to be proper following appeal, the extrapolated amount will decrease proportionally. At some point during the appeals process, the payment error rate will likely fall below the undefined threshold of “high;” however, it is unclear when or even whether such a determination may be reviewed, leaving Community open to the possibility of impermissible

²² See 42 U.S.C. § 1395ddd(f)(3).

extrapolation in the absence of the statutory prerequisites. Further, Community anticipates that at least some of the estimated overpayment amount may be recouped while some appeals are pending at the ALJ level. Given the high value of OIG's current estimate, the application of extrapolation will have a disproportionate and extremely detrimental financial impact on Community.

B. OIG's Use of Extrapolation for IRF Claims Is Inappropriate

As demonstrated by the extensive and detailed process for approving patients for admission to Community's IRF, the requirements for coverage of IRF services under Medicare are very specific—much more specific than almost any other item or service covered by the program. By regulation, careful individualized determinations must be made by a specialized physician in order for IRF care to be reimbursable. The nature of the admissions process makes IRF claims particularly inappropriate for extrapolation.

"[T]he essence of inferential statistics is that one may confidently draw inferences about the whole from a representative sample of the whole."²³ The permissibility of statistical sampling turns on "the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action."²⁴ OIG did not identify routine and related documentation errors that might serve as some indicator of errors in other claims within the universe.

Instead, OIG made medical necessity determinations, and the nature of these claims requires an individualized determination that cannot be replaced by an examination of a sample that is then projected to the whole. When medical necessity is involved, courts have rejected the use of extrapolation.²⁵ Because "each and every claim at issue" was "fact-dependent and wholly unrelated to each and every other claim," and determining eligibility for "each of the patients involved a highly fact-intensive inquiry involving medical testimony after a thorough review of the detailed medical chart of each individual patient," the court found the case was not "suited for statistical sampling."²⁶ Thus, extrapolating the alleged errors in the sampled IRF claims to the entirety of IRF claims submitted for reimbursement by Community during the relevant time period is unsupported. Based on the fact-specific and individualized nature of the admission

²³ *United States v. Pena*, 532 F. App'x 517, 520 (5th Cir. 2013).

²⁴ *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1046 (2016); see *In re Chevron U.S.A., Inc.* 109 F.3d 1016, 1020 (5th Cir. 1997).

²⁵ *United States ex rel. Wall v. Vista Hospice Care, Inc.*, No. 3:07-CV-00604-M, 2016 WL 3449833, at *11-13 (N.D. Tex. June 20, 2016); *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. CA 0:12-3466-JFA, 2015 WL 3903675, at *2 (D.S.C. June 25, 2015).

²⁶ *Agape Senior Cmty., Inc.*, at *2, *8; see also *U.S. v. Medco Phys. Unlimited*, No. 98-C-1622, 2000 U.S. Dist. LEXIS 5843, at *23 (N.D. Ill. Mar. 15, 2000).

errors alleged by OIG, only a claim-by-claim examination and determination process is appropriate for IRF claims.

C. OIG's Sampling Methodology Is Flawed

In preparing its response, Community retained Dr. George McCabe, a highly qualified and experienced statistician, to review OIG's IRF sampling methodology. Dr. McCabe determined that the OIG sample does not reflect the distribution of cases admitted to Community's IRF. (See Appendix 5.) Dr. McCabe compared the distribution of Community's impairment group codes ("IGCs") during the timeframe for the audit with the IGC distribution found in the OIG sample. Dr. McCabe identified a statistically significant discrepancy between the two. Therefore, Dr. McCabe determined that OIG's sample "cannot be used to provide an unbiased estimate of overpayments of claims" from Community. (See Appendix 5.)

In addition, OIG admits to removing "claims with certain patient discharge status codes" and "claims with specific diagnosis and HCPCS codes" from the sample frame.²⁷ OIG does not, however, disclose which specific discharge status codes and diagnosis codes were removed from the sample frame. It is possible that OIG's removal of these claims resulted in the IGC distribution discrepancy identified by Dr. McCabe. OIG may have impermissibly skewed the sample frame, compromising the randomness of the sample. Given the medical reviewer's stated bias against certain types of diagnoses (e.g., debility), a high prevalence of these claims in the sample as a result of "cherry picking" the claims could have improperly weighted the end results of the audit against Community and resulted in a higher error rate. It is impossible to determine the actual effect of OIG's removal of certain claims without more information about which specific types of claims that were removed, but it is significant that OIG's removal of claims whittled the sampling frame down substantially—from nearly 9,000 claims to just 2,510 claims.

Further diminishing the integrity of the sample and sampling frame, Community's IRF underwent a number of audits covering the same two-year time period (i.e., 2015 and 2016). As noted above, the SMRC and the MAC have audited 203 IRF claims with dates of service falling between 2014 and 2016. The SMRC and the MAC have already determined that 149 of those claims were medically necessary and 87% of the remaining 47 will most likely be resolved in favor of Community at the ALJ level. OIG has made no representation as to whether it excluded these claims from the sampling frame. If these claims were not excluded, simply removing them would unjustly skew the error rate unless a new sample is selected and reviewed after their removal. With respect to the claims that were denied under those other audits and remain pending appeal, inclusion of those claims in the sampling frame also unfairly skews any

²⁷ Appendix B of the Draft Report.

estimated overpayment and could lead to an unjust double recovery of the amount originally paid for those claims.

While OIG stratified its sample into six risk areas, it is not clear whether that stratification was taken into account when estimating the final overpayment. The error rates, number of claims, and dollar value of the claims in each stratum varied significantly, with error rates as low as zero and as high as 76% (based on dollar value of claims). If the error rate of each stratum was applied broadly across the entire universe of claims (or even sampling frame), this could create a highly inaccurate estimate of overpayments. At a minimum, OIG should have applied the error rate for each stratum separately and only to that stratum in the sampling frame or universe and then added the resulting overpayment estimates together.

Finally, one of the strata contained only a single claim. It is entirely inappropriate to make an estimate of total overpayments relating to this stratum as the entire sampling frame is encompassed in OIG's review of that single claim. Applying the resulting error rate from that stratum—which is tied to a fairly uncommon and, in this case, singular event—to the rest of the sampling frame is wholly inappropriate.

Given the known errors and potential errors in OIG's sampling methodology, Community requests that OIG abandon its estimated overpayment, or at minimum, recalculate the estimate prior to issuing its final report.

VII. Community's Response to OIG's Recommendations

OIG's Draft Report makes three recommendations. First, OIG recommends that Community refund \$22,051,602. Second, OIG recommends that Community exercise reasonable diligence in identifying and refunding any additional overpayments similar to those identified by OIG's audit, in accordance with the "60-day rule." Third, OIG recommends that Community strengthen its controls to ensure full compliance with Medicare requirements. Because Community disagrees with OIG's findings, Community also largely disagrees with these recommendations.

Community has already repaid 20 of the 23 DRG claims. Community intends to exercise its right to appeal the remaining three claims and has not refunded those claims. Similarly, because Community disputes all of OIG's determinations for the IRF claims, Community intends to appeal all of those claims and has not repaid any of them.

Regarding the 60-day rule, Community has conducted DRG coding audits. Any overpayments identified during those audits have been (or will be) refunded. As to Community's IRF claims, OIG's determinations are in error, and Community intends to appeal

100% of any denials. Community does not agree that it has any duty to investigate further under the 60-day rule. However, as noted in its ICQ response to OIG, Community routinely carries out auditing and compliance monitoring related to its IRF. These audits will continue in the normal course of business for Community.

Community's corrective actions to DRG coding are discussed above and in its ICQ response. Community strongly contends that its IRF admission practices fully comply with Medicare requirements. It has a strong three-tiered process for assessing patients for admission and, as confirmed by OIG's medical reviewer, complies with all documentation requirements for IRF services. Nonetheless, as explained in its ICQ response, Community has taken additional steps to strengthen its documentation and compliance standards, including providing continued education and training to ensure detailed documentation of medical necessity in the preadmission screening; providing periodic refresher education and training to physicians on IRF documentation requirements; developing a coding and documentation reference guide for completing the preadmission screening organized by Impairment Group Code ("IGC"); and revising standardized documentation formats for physicians and the rest of the rehabilitation team. If OIG has additional, specific process suggestions, we would be happy to consider implementing them.

VIII. Conclusion

Community strongly disagrees with the vast majority of OIG's conclusions and recommendations. From its selection of Community, to its reliance on a likely unqualified medical reviewer, to its improper use of overpayment estimation, OIG's audit of Community is fundamentally flawed. If finalized, OIG's report will improperly harm Community's reputation and finances, jeopardizing its patient care mission and its ability to continue serving the health care needs of the community. OIG and Community had many opportunities to work together to reach understanding on many of the issues identified in this response, but OIG refused to meaningfully consider Community's evidence and arguments to the contrary. Community sincerely hopes that this final set of comments and feedback, as well as its thorough rebuttal of the individual IRF determinations, will lead OIG to correct its serious errors in the final report of this audit.

Sincerely,

/Luis F. Molina/

Luis F. Molina
Chief Executive Officer
Community Hospital