

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**MEDICARE HOSPITAL PROVIDER
COMPLIANCE AUDIT:
SAINT FRANCIS HEALTH CENTER**

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Office of Inspector General

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Report in Brief

Date: March 2020

Report No. A-07-17-05102

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



Why OIG Did This Audit

This audit is part of a series of hospital compliance audits. 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 2016, Medicare paid hospitals \$170 billion, which represents 46 percent of all fee-for-service payments for the year.

Our objective was to determine whether Saint Francis Health Center (the Hospital) complied with Medicare requirements for billing inpatient services on selected types of claims from January 1, 2015, through December 31, 2016.

How OIG Did This Audit

We selected for review a stratified random sample of 100 inpatient claims with payments totaling \$1.4 million for our 2-year audit period.

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and referred each sampled claim to medical review to determine whether the claim was supported by the medical record.

Medicare Hospital Provider Compliance Audit: Saint Francis Health Center

What OIG Found

The Hospital complied with Medicare billing requirements for 49 of the 100 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 51 claims, resulting in overpayments of \$707,118 for calendar years 2015 and 2016.

On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$5.5 million for the audit period.

What OIG Recommends and Hospital Comments

We recommend that the Hospital refund to the Medicare contractor \$5.5 million of the estimated overpayments for the claims incorrectly billed that are within the Medicare reopening period; for the remaining portion of the estimated \$5.5 million overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and strengthen controls to ensure full compliance with Medicare requirements.

The Hospital agreed that four of the nine inpatient claims that we found to be in error were incorrectly coded. The Hospital disagreed with the remainder of our findings, including our extrapolated overpayment and our recommendations. The Hospital stated that our independent medical review contractor committed numerous errors when making its determinations.

We asked our contractor to review the Hospital's comments and the supplemental documentation that it provided. Based on the results of this additional medical review and our evaluation, we revised our determinations, adjusting the total number of reportable error claims in our audit period from 53 to 51, and revised our findings and the associated recommendations accordingly. We maintain that our remaining findings and recommendations are valid. Our contractor examined all of the material in the medical records and the documentation submitted by the Hospital, applied relevant criteria, and reached carefully considered conclusions. In addition, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid.

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INTRODUCTION

WHY WE DID THIS AUDIT

This audit is part of a series of hospital compliance audits. 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 2016, Medicare paid hospitals \$170 billion, which represents 46 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 Saint Francis Health Center (the Hospital) complied with Medicare requirements for billing inpatient services on selected types of claims from January 1, 2015, through December 31, 2016.

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 uses Medicare contractors to, among other things, process and pay claims submitted by hospitals.

Hospital Inpatient Prospective Payment System

Under the inpatient prospective payment system, CMS pays hospital costs at predetermined rates for patient discharges. 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. In addition to the basic prospective payment, hospitals may be eligible for an additional payment, called an outlier payment, when the hospital's costs exceed certain thresholds.

Hospital Inpatient Rehabilitation Facility 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 patients' ability to function. Section 1886(j) of the Social Security Act (the Act) established the Medicare prospective payment system for rehabilitation facilities. CMS implemented this system for cost reporting periods beginning on

or after January 1, 2002. Under this system, CMS established a Federal prospective payment rate for each of the distinct case-mix groups (CMGs). The assignment to a CMG is based on the beneficiary's clinical characteristics and expected resource needs.

Hospital Claims at Risk for Incorrect Billing

Our previous work at other hospitals identified these types of hospital claims, among others, that were at risk for noncompliance:

- IRF claims and
- inpatient claims billed with high-severity-level DRG codes.

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 audit.

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 (§§ 1815(a) and 1833(e)).

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* 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 U.S. Department of Health and Human Services (HHS), Office of Inspector General (OIG) believes that this audit report constitutes credible information of potential overpayments. Providers who receive notification of these potential overpayments must (1) exercise reasonable diligence to investigate the potential overpayment, (2) quantify any 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).¹

¹ The Act § 1128J(d); 42 CFR part 401 subpart D; 42 CFR §§ 401.305(a)(2) and (f); and 81 Fed. Reg. 7654, 7663 (Feb. 12, 2016).

Saint Francis Health Center

The Hospital is a 253-bed hospital located in Topeka, Kansas. According to CMS's National Claims History (NCH) data, Medicare paid the Hospital approximately \$74.5 million for 7,807 inpatient claims between January 1, 2015, and December 31, 2016 (audit period).

HOW WE CONDUCTED THIS AUDIT

Our audit covered \$16,006,278 in Medicare payments to the Hospital for 1,412 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 inpatient claims with payments totaling \$1,404,433.²

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and referred each sampled claim to medical review to determine whether the claim was supported by the medical record. 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 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 scope and methodology.

FINDINGS

The Hospital complied with Medicare billing requirements for 49 of the 100 inpatient claims we reviewed. However, the Hospital did not fully comply with Medicare billing requirements for the remaining 51 claims, resulting in overpayments of \$707,118 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 \$5,533,169 for the audit period. See Appendix B for our statistical sampling methodology, and Appendix C for our sample results and estimates.

² This dollar amount differs from the amount conveyed in our draft report. Our statistical sample (Appendix B) included two inpatient rehabilitation claims that were reviewed by the Hospital's Medicare contractor. For estimation purposes for both our draft and final reports, these two claims remained in our sample; we coded them as having zero (0) dollars for overpayment. Our draft report, though, did not include the value of these two claims—that is, their associated payments—as part of the total reflected in this dollar amount. To avoid confusion, for this final report we have revised our description of this amount, here and in Appendices A and C, to include the paid amounts for these two claims. See also our discussion in "Use of Statistical Sampling" later in this report.

BILLING ERRORS ASSOCIATED WITH INPATIENT CLAIMS

The Hospital incorrectly billed Medicare for 51 of the 100 inpatient claims that we reviewed. These errors resulted in overpayments of \$707,118.

Incorrectly Billed Inpatient Rehabilitation Facility Claims

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)).

The *Medicare Benefit Policy Manual* (the Manual) states: “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” (the Manual, Pub. No. 100-02, chapter 1, § 110).

The Manual also 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).

For an IRF claim to be considered reasonable and necessary, Federal regulations require that there be a reasonable expectation that, at the time of admission, the patient (1) required the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally required and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) was sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; and (4) required physician supervision by a rehabilitation physician (42 CFR § 412.622(a)(3)(i-iv)).

Federal regulations require that the patient’s medical record must contain certain documentation to ensure that the IRF coverage requirements are met. The record must include (1) a comprehensive preadmission screening, (2) a post-admission physician evaluation, and (3) an individualized overall plan of care (42 CFR § 412.622(a)(4)(i-iii)).

For 44 of the 70 selected inpatient rehabilitation claims selected from Stratum 1 (Appendix B), the Hospital incorrectly billed Medicare Part A for beneficiary stays that did not meet Medicare criteria for acute inpatient rehabilitation. Specifically, 44 claims did not meet medical necessity requirements. Additionally, one of the claims that did not meet medical necessity requirements also did not comply with Medicare documentation requirements as specified in

chapter 1 of the Manual, because there was no documentation of weekly multidisciplinary team meetings.

The Hospital disagreed with the findings for all 44 claims. Specifically, the Hospital stated that each of these 44 claims was a fully supported IRF claim that complied with Medicare coverage and payment criteria. As a result of these errors, the Hospital received overpayments of \$686,893.

Incorrectly Billed Diagnosis-Related-Group Codes

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 *Medicare Claims Processing Manual* states: “In order to be processed correctly and promptly, a bill must be completed accurately” (chapter 1, § 80.3.2.2).

For 7 of the 30 selected inpatient high-severity-level DRG code claims selected from Stratum 2 (Appendix B), the Hospital submitted claims to Medicare that were incorrectly coded, resulting in incorrect DRG payments to the Hospital. Specifically, the medical records did not support certain diagnosis codes.

The Hospital agreed with the findings for four of the claims and stated that these findings were generally attributable to human error. However, it disagreed with the findings for the remaining three claims. As a result of the errors associated with the seven claims that we identified, the Hospital received overpayments of \$20,225.

INADEQUATE CONTROLS

The errors discussed above 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.

OVERALL ESTIMATE OF OVERPAYMENTS

The combined overpayments associated with the incorrectly billed inpatient claims we identified totaled \$707,118. On the basis of our sample results, we estimated that the Hospital received overpayments of at least \$5,533,169 for the audit period.

RECOMMENDATIONS

We recommend that Saint Francis Health Center:

- refund to the Medicare contractor \$5,533,169 of the estimated overpayments for the claims incorrectly billed that are within the Medicare reopening period;³
- for the remaining portion of the estimated \$5,533,169 overpayment for claims that are outside of the Medicare reopening period, exercise reasonable diligence to identify and return overpayments, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation;
- exercise reasonable diligence to identify and return any additional similar overpayments outside of our audit period, in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation; and
- strengthen controls to ensure full compliance with Medicare requirements.

AUDITEE COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In written comments on our draft report, the Hospital agreed that four of the nine inpatient claims billed with high-severity-level DRG codes that we found to be in error were incorrectly coded.⁴ The Hospital disagreed with the remainder of our findings, including our extrapolated overpayment, and with each of our recommendations. The Hospital stated that our independent medical review contractor, in reviewing the IRF claims, committed numerous errors that included using an incorrect standard of review, basing findings on factually incorrect statements, ignoring important clinical information, taking an approach that runs contrary to commonly accepted clinical standards, concluding that admissions were inappropriate despite finding that documentation requirements were met, using 20/20 hindsight, and failing to consider positive patient progress and outcomes. The Hospital also stated that our medical review contractor made multiple errors in determining the five coding errors for the high-

³ 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 Medicare contractor 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 Parts A and B appeals process has five levels, including a contractor redetermination, a reconsideration by a Qualified Independent Contractor, and a decision by the Office of Medicare Hearings and Appeals. If a provider exercises its right to an appeal, it does not need to return funds paid by Medicare until after the second level of appeal. An overpayment based on extrapolation is re-estimated depending on the result of the appeal.

⁴ We stated in our draft report that we found that nine inpatient claims with high-severity-level DRG codes were incorrectly coded. We revised that number to seven in this final report.

severity-level DRG codes with which the Hospital disagreed. Lastly, the Hospital stated that our use of extrapolation was contrary to law and added that it has no duty under the 60-Day rule, because our report does not constitute credible information of potential overpayments and because the Medicare appeals process has not run its course.

The Hospital's comments, from which we have removed various enclosures due to their volume and because some of them contain personally identifiable information, appear as Appendix D. We are providing the Hospital's comments in their entirety to CMS. The enclosures included claim-by-claim documentation related to the claims that our draft report had questioned, documentation which, the Hospital said, demonstrated the errors in our medical review.

To address the Hospital's concerns regarding the work performed by our independent medical review contractor, we asked the contractor to review the Hospital's written comments on our draft report and the supplemental documentation that it provided.

Based on the results of this additional medical review and our evaluation of the Hospital's written comments and its additional and supplemental documentation, we revised our determinations for this final report. Specifically, we adjusted the total number of reportable error claims in our audit period from 53 to 51 and revised our findings and the associated recommendations accordingly. We maintain that our remaining findings and recommendations are valid, although we acknowledge the Hospital's rights to appeal the findings. Below are more detailed discussions of the bases for the Hospital's disagreements with our findings and recommendations as well as our responses.

INCORRECTLY BILLED INPATIENT REHABILITATION FACILITY CLAIMS

Auditee Comments

The Hospital stated that it engaged an independent healthcare consultant to review all 44 of the inpatient rehabilitation claims in our findings; the consultant, it said, found that all of these claims were correctly billed and documented and that all met Medicare coverage and medical necessity requirements. The Hospital added that post-admission documentation established that each patient received and benefitted from an interdisciplinary team approach to care during his or her admission. The Hospital also said that we should have considered this post-admission information in accordance with a paragraph in the Manual, chapter 1, § 10, which discussed Quality Improvement Organization (QIO) review. The Hospital stated that our findings turned on whether there was a reason to think that an intensive rehabilitation therapy program would significantly impact a patient's condition differently compared with therapy provided at a less intensive level (lower level of care). The Hospital added that "it is highly unusual to find across-the-board disagreement [between OIG and a healthcare provider] with respect to 100 percent of the claims at issue. The results of this review raise significant concerns regarding the objectivity of the [independent medical review contractor] and the conclusions reached in the Draft Report."

Office of Inspector General Response

We maintain that all of our findings regarding inpatient rehabilitation claims, and the associated recommendations, remain valid because the 44 claims did not meet medical necessity requirements. Specifically, IRF services for these beneficiaries were not considered reasonable and necessary because these beneficiaries (1) did not require the active and ongoing therapeutic intervention of multiple therapy disciplines; (2) generally did not require and could not reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program; (3) were not sufficiently stable at the time of admission to the IRF to be able to actively participate in the intensive rehabilitation program; or (4) did not require physician supervision by a rehabilitation physician.

Our independent medical review contractor did not determine the Medicare medical necessity of IRF claims based on whether a lower level of care was more appropriate. The contractor prepared detailed medical review determination letters that documented relevant facts and the results of the contractor's analysis. These were provided to the Hospital before we issued our draft report. Although the contractor included the comment "lower level of care more appropriate" in the determination letters, this was not the standard applied in making a medical necessity determination for IRF admissions. Noting that a lower level of care could have been more appropriate was a comment by the physician reviewer, based on that individual's review of the claims in which the medical record demonstrated that the IRF admission was not medically necessary. That comment was not, as the Hospital posited, a basis for the medical necessity determination. As reflected in the rationale section of the determination letters, the medical review contractor never stated that the IRF admission was not medically necessary because a less intense level of care was medically indicated. Instead, it was an observation based on the lack of support for the IRF admission in the medical records. The Hospital's statement that our medical review contractor denied IRF claims on the basis that a lower level of care was more appropriate is without merit.

Further, the Hospital's statement that the IRF admissions were supported by evidence that each patient received and benefitted from an interdisciplinary team approach to care is flawed. The medical necessity of an IRF admission, as acknowledged by the Hospital, is not based on the course of the stay, but on whether the documentation supported a reasonable expectation, at the time of admission, that the patient met Medicare criteria for an IRF admission. There is no basis under Medicare rules or CMS guidance for relying on progress during, or the outcome from, an IRF admission to justify the decision to admit the patient in the first instance. The Hospital is incorrect in its statement that that we should have considered post-admission information in accordance with a paragraph in the Manual (chapter 1, § 10) that discussed QIO review. This manual provision does not alter IRF coverage requirements. It simply acknowledges that QIOs, in reviewing inpatient admissions, may determine from post-admission documentation that, although a patient may not have required an inpatient level of care on admission, a patient's condition may change during the stay such that inpatient care

becomes medically necessary.⁵ Accordingly, the Hospital's statement, that patients' receiving and benefitting from an interdisciplinary team approach support the appropriateness of the decision to admit the patient to the IRF, is without merit.

Our independent medical review contractor examined all of the material in the medical records and the documentation submitted by the Hospital and carefully considered this information to determine whether the Hospital billed the claims in compliance with selected Medicare requirements. The contractor similarly evaluated the additional documentation that the Hospital provided after issuance of our draft report. For all medical review, the independent medical review contractor applied the relevant criteria and reached objective, carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. The fact that the Hospital disagreed with all of our findings regarding these 44 claims does not, and should not, call into question the objectivity of our independent medical review or of the conclusions reached in our report.

INCORRECTLY BILLED DIAGNOSIS-RELATED GROUP CODES

Auditee Comments

For the nine inpatient high-severity-level DRG code claims that we questioned in our draft report (footnote 4), the Hospital agreed that four of these claims were incorrectly coded but stated that the other five claims were correctly coded, for the reasons stated in the claim-by-claim documentation it submitted with its comments. The Hospital added that even if all nine of these claims were incorrectly coded, we incorrectly calculated the resulting overpayment amount.

Office of Inspector General Response

Based on the information that the Hospital provided and the conclusions of our independent medical review contractor's additional medical review, we revised the findings related to high-severity-level DRG code claims (and the associated recommended disallowance) to specify that seven claims, rather than nine, involved beneficiaries who did not meet the Medicare coverage criteria as billed. We used CMS pricing software to recalculate the dollar amount associated with the seven claims in this final report.

Our independent medical review contractor examined all the material in those records and the documentation submitted by the Hospital and carefully considered this information to determine whether the Hospital billed the claims in compliance with selected billing requirements. The contractor similarly evaluated the additional documentation that the Hospital provided after issuance of our draft report. For all medical review, the independent medical review contractor reached carefully considered conclusions as to whether the services met coverage, medical necessity, and coding requirements. For example, with respect to three

⁵ Quality Improvement Organization Manual, chapter 4, § 4110.B.

of the claims for which the Hospital disagreed with our findings, the most recent determinations by our independent medical review contractor noted that although the principal diagnoses were substantiated, the secondary diagnoses were not.

Accordingly, having revised our findings and the associated recommendation with respect to the nine high-severity-level DRG code claims that we questioned in our draft report, we maintain that our findings for the remaining seven claims conveyed in this final report, and the amount in our revised recommendation, are valid.

USE OF STATISTICAL SAMPLING

Auditee Comments

For both the inpatient rehabilitation claims and the high-severity-level DRG code claims in our findings, the Hospital disagreed with the statistical sampling methodology that led to our recommended disallowance. For both types of claims, the Hospital cited to a provision of the Act that states: “a Medicare contractor may not use extrapolation to determine overpayment amounts” unless “there is a sustained or high level of payment error” On this basis and that of an incorporating provision in CMS’s *Medicare Program Integrity Manual*, the Hospital pointed to its disagreement with all 44 inpatient rehabilitation claims and with 5 of the 9 high-severity-level DRG code claims as indicative that it did not have a high level of payment error. The Hospital added that because ours was a single audit with a single audit period, our report did not provide evidence of a sustained level of payment error.

With respect to the extrapolation of inpatient rehabilitation claims, the Hospital cited CMS’s *Medicare Program Integrity Manual* and stated that each element in a statistical sample must have an equal opportunity of being selected and must be representative of the original universe. The Hospital stated that by not removing two claims from the sampling frame that had already been reviewed by the Hospital’s Medicare contractor, we violated that requirement because those two claims did not have an equal opportunity of being selected. The Hospital said that, as evidence for that statement, we removed these two claims from the sample after learning of their existence. The removal of these two claims, according to the Hospital, “tainted” the entire sample, and the results of the review of that sample can therefore not be extrapolated.

Office of Inspector General Response

We maintain that our revised findings and the associated recommendations, to include the extrapolated disallowance conveyed in our first recommendation, are valid. The Hospital is within its rights to appeal the recommended disallowance through the Medicare appeals process (footnote 3).

With respect to the Hospital’s reference to the Act and CMS’s *Medicare Program Integrity Manual* in its statements about the circumstances under which extrapolation is allowed, the

requirements cited by the Hospital apply only to samples selected *by Medicare contractors*. See the Act § 1893(f)(3); *Medicare Program Integrity Manual*, Pub. No. 100-08, chapter 8.4, § 8.4.1.2 (effective January 2, 2019).

Regarding the Hospital's other objections to our statistical sampling and extrapolation methodology, Federal courts have consistently upheld statistical sampling and extrapolation as a valid means to determine overpayment amounts in Medicare and Medicaid. 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).

The legal standard for use of sampling and extrapolation is that it must be based on a statistically valid methodology, not the most precise methodology. 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). We properly executed our statistical sampling methodology in that we defined our sampling frame and sampling unit, randomly selected our sample, applied relevant criteria in evaluating the sample, and used statistical software (i.e., RAT-STATS) to apply the correct formulas for the extrapolation. This approach results in an unbiased point estimate and a conservative lower limit.

Contrary to the Hospital's statement that the sample was rendered invalid by the inclusion of two inpatient rehabilitation claims that were reviewed by the Hospital's Medicare contractor, we did not ignore these claims, remove them from the sample, or otherwise compromise the integrity of the sample design. Prior to pulling the sample, we excluded from our sampling frame all claims that we identified as having been reviewed by another entity. However, after pulling the sample, we identified these two claims as being under review by a Medicare contractor. The identification of these claims did not change the known probability that each item in the sampling frame had of being selected. We fully accounted for these two claims by treating them in the same manner that we would treat any other claims for which the provider has no potential financial liability as a result of this audit: we left the claims in the sample, and we coded them as having zero dollars in overpayments. See footnote 2.

IDENTIFICATION AND RETURN OF SIMILAR OVERPAYMENTS OUTSIDE OF THE AUDIT PERIOD IN ACCORDANCE WITH THE 60-DAY RULE

Auditee Comments

In its comments on both the inpatient rehabilitation claims and the high-severity-level DRG code claims in our findings, the Hospital asked that we remove our second recommendation

from this report. The Hospital stated that it does not believe that our report constitutes credible information of potential overpayments outside of the audit period (footnote 1). Specifically, the Hospital believes that the audit payment error associated with the primary finding (IRF claims) is zero. Moreover, for both types of claims in our findings, the Hospital said that any errors were not the result of systematic or programmatic issues or errors.

Office of Inspector General Response

We maintain that all of our findings, as revised, are valid, for the reasons given above in our responses to the Hospital's other comments and for the reasons given earlier in our findings themselves. These reasons are well supported by the legal criteria we have cited and by our independent medical review contractor's determinations. Therefore, we maintain that our second recommendation, regarding the identification and return of similar overpayments outside of the 4-year claim-reopening period in accordance with the 60-day rule, remains valid as well.

APPENDIX A: AUDIT SCOPE AND METHODOLOGY

SCOPE

Our audit covered \$16,006,278 in Medicare payments to the Hospital for 1,412 claims that were potentially at risk for billing errors. We selected for review a stratified random sample of 100 inpatient claims with payments totaling \$1,404,433 (footnote 2). Medicare paid these 100 claims during our audit period.

We focused our audit on the risk areas identified as a result of prior OIG audits at other hospitals. We evaluated compliance with selected billing requirements and referred each sampled claim to medical review to determine whether the claim was supported by the medical record.

We limited our review of the Hospital's internal controls to those applicable to the inpatient 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 NCH file. Our OIG, Office of Audit Services (OAS), Advanced Audit Techniques Staff determined that Medicare NCH claims data are reliable data if they are obtained from the OIG Data Warehouse or CMS's Data Extract System. We did not separately assess the completeness of the file for this audit as the use of the data and the results of the work would not lead to an incorrect or unintentional message based on the intended use of the data.

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 audit work from August 2017 through November 2019.

METHODOLOGY

To accomplish our objective, we:

- reviewed applicable Federal laws, regulations, and guidance;
- extracted the Hospital's inpatient paid claims data from CMS's NCH 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 100 inpatient claims totaling \$1,404,433 for detailed review (Appendix B);

- obtained and reviewed billing and medical record documentation provided by the Hospital to support the selected claims;
- used an independent medical review contractor to determine whether 100 claims contained in the sample were reasonable and necessary and met Medicare coverage 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 overpayment to the Hospital (Appendix C); and
- discussed the results of our audit with Hospital officials on July 26, 2018.

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

TARGET POPULATION

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

SAMPLING FRAME

The sampling frame consisted of a database of 1,412 inpatient claims, valued at \$16,006,277.61, from CMS's NCH file.⁶

SAMPLE UNIT

The sample unit was a Medicare paid inpatient claim.

SAMPLE DESIGN

We used a stratified random sample. We stratified the sampling frame into two strata based on Medicare risk area. Inpatient rehabilitation claims were in stratum 1 and inpatient claims billed with high-severity-level DRG codes were in stratum 2. All claims were unduplicated, appearing in only one area and only once in the entire sampling frame.

Stratum	Dollar Range of Frame Units	Number of Frame Units	Sample Size	Dollar Value of Frame Units
1	\$1,494.90 to \$58,764.49	610	70	\$9,906,105
2	\$1,916.59 to \$42,372.91	802	30	6,100,173
Totals		1,412	100	\$16,006,278

SAMPLE SIZE

We randomly selected 70 unique inpatient claims from stratum 1 and 30 from stratum 2. Our total sample size was therefore 100 inpatient claims.

SOURCE OF RANDOM NUMBERS

We generated the random numbers using the OIG, OAS, statistical software.

⁶ Our sampling frame excluded claims associated with (1) claims with certain discharge status and diagnosis codes, (2) paid claims of \$1,000 or less, and (3) claims associated with error codes 534 or 540 (claims that are excluded from further review, such as Recovery Audit Contractor-reviewed claims).

METHOD OF SELECTING SAMPLE ITEMS

We consecutively numbered the sample units in the frame from 1 to 610 for stratum 1 and from 1 to 802 for stratum 2. A statistical specialist generated 70 random numbers for stratum 1 and 30 random numbers for stratum 2. With these random numbers, we selected the corresponding frame items for review.

ESTIMATION METHODOLOGY

We used the OIG, OAS, statistical software to calculate our estimates. We used the lower limit of the 90-percent confidence interval to estimate the amount of improper Medicare payments in our sampling frame during the audit period (Appendix C).

APPENDIX C: SAMPLE RESULTS AND ESTIMATES

SAMPLE RESULTS

Stratum	Frame Size (Claims)	Value of Frame	Sample Size	Value of Sample	Number of Incorrectly Billed Claims in Sample	Value of Overpayments in Sample
1	610	\$9,906,105	70	\$1,195,778	44	\$686,893
2	802	6,100,173	30	208,655	7	20,225
Total	1,412	\$16,006,278	100	\$1,404,433⁷	51	\$707,118

Estimates of Overpayments for the Audit Period
Limits Calculated for a 90-Percent Confidence Interval

Point Estimate	\$6,526,461
Lower limit	5,533,169
Upper limit	7,519,753

⁷ See Footnote 2.



November 14, 2018

BY HHS-OIG Delivery Server

Mr. Patrick J. Cogley
 Regional Inspector General for Audit Services
 HHS-OIG Office of Audit Services, Region VII
 601 East 12th Street, Room 429
 Kansas City, MO 64106

Re: *Medicare Compliance Review of Saint Francis Health Center,*
 Report Number: A-07-17-05102

Dear Mr. Cogley:

Saint Francis Health Center ("Saint Francis"), a non-profit, tax-exempt, faith-based acute care hospital located in Topeka, Kansas, respectfully submits this letter in response to the U.S. Department of Health and Human Services, Office of Inspector General ("HHS-OIG") draft audit report entitled, *Medicare Compliance Review of Saint Francis Health Center*, Report No. A-07-17-05102, dated September 17, 2018 ("Draft Report").¹ The Draft Report addresses HHS-OIG's review of two distinct types of claims: (1) Inpatient Rehabilitation Facility claims ("IRF Claims"), and (2) inpatient claims relating to high-severity-level diagnostic-related group codes ("High Severity Claims"). As detailed below, Saint Francis believes the Draft Report contains multiple legal and factual errors with respect to both types of claims. In light of these errors, Saint Francis respectfully requests that HHS-OIG revisit and re-review the process and findings of its contract auditor ("Contract Auditor") before finalizing the Draft Report.

Section I
Summary of Draft Report

The Draft Report is the result of an audit ("Audit") undertaken by HHS-OIG as part of a national initiative designed to determine hospital compliance with various Medicare billing requirements. Specifically, the Audit covered IRF and High Severity Claims with 2015 and 2016 dates of services ("Audit Period"). In total, HHS-OIG's Contract Auditor set out to review 70 IRF Claims and 30 High Severity Claims, collectively representing \$1,380,673 in Medicare reimbursement. In actuality, the Audit Contractor only reviewed 68 IRF Claims, and not the 70 referenced in the Draft Report. As discussed further below, this is because two of the IRF Claims in the sample already were subject to a separate

¹ Saint Francis is the former owner and operator of a non-profit, tax-exempt, faith-based, 378-bed acute care hospital located at 1700 SW 7th St., Topeka, Kansas. The Saint Francis CMS Certification Number ("CCN") was 177201, its National Provider Identifier ("NPI") was 1912902735, and its tax identification number ("TIN") was 48-0547719. On September 29, 2017, Saint Francis entered into an Asset Purchase Agreement (the "APA"), pursuant to which Saint Francis agreed to sell most of its assets to Topeka Health System, LLC, a Delaware limited liability company ("THS") d/b/a Topeka Hospital, LLC. The transaction was fully consummated on November 1, 2017. Pursuant to the terms of the APA, Saint Francis is responsible for addressing and resolving any alleged hospital overpayments. Thus, Saint Francis (the former owner) and not THS (the current owner) is responsible for addressing and responding to the Draft Report and any subsequent appeals related to these claims.

ongoing review by Saint Francis's Medicare Administrative Contractor ("MAC") and, thus, should not have been included in the sample frame from which the 70-claim sample was drawn. The Contract Auditor concluded that:

- 44 of the 70 IRF Claims did not comply with the relevant Medicare billing requirements, resulting in alleged overpayments totaling \$686,893,² and
- Nine of the 30 High Severity Claims did not comply with the relevant Medicare billing requirements, resulting in alleged overpayments totaling \$23,289.³

As set forth in the Draft Report, HHS-OIG extrapolated these findings and recommended that Saint Francis:

- "refund to the Medicare contractor \$5,614,830 in estimated overpayments for the [Audit Period] for claims that it incorrectly billed" ("Extrapolation Recommendation"),
- "exercise reasonable diligence to identify and return any additional similar overpayments outside of [the Audit Period], in accordance with the 60-day rule, and identify any returned overpayments as having been made in accordance with this recommendation" ("60-Day Rule Recommendation"), and
- "strengthen controls to ensure full compliance with Medicare requirements."⁴

Section II

Executive Summary of Saint Francis Response

As set forth above, the Contract Auditor committed numerous errors in connection with its review of the IRF Claims. These errors include:

1. **Incorrect Standard of Review.** The Audit process and conclusions are invalid because the Contract Auditor created and applied a standard for IRF admission that is not supported by the relevant authorities, is contrary to well-established medical practice, and would be impossible for any provider to apply in practice.
2. **Factual Errors.** Many of the Audit findings are based on factually incorrect statements regarding the relevant patients' medical records.
3. **Factual Omissions.** In a number of cases, the Audit findings ignore important clinical information in the medical record. For instance, the Contract Auditor sometimes fails to take into account a patient's particular circumstances and co-morbidities, and the impact these had on the rehabilitation process.
4. **Incorrect Clinical Approach.** The approach taken by the Contract Auditor runs contrary to the standards commonly accepted by physiatrists supervising patient rehabilitation.

² HHS-OIG Draft Report, Medicare Compliance Review of Saint Francis, Report No. A-07-17-05102 (Sept. 17, 2018) (the "Draft Report").

³ *Id.* at 5.

⁴ *Id.* at 6.

5. **Confirmation of Facts Supporting Admission.** Although the Contract Auditor largely concedes that Saint Francis has met the substantial documentation requirements necessary to ensure appropriate IRF admissions, the Contract Auditor nevertheless concludes that those same admissions are inappropriate.
6. **Inappropriate Use of 20/20 Hindsight.** Under the relevant authorities, the key finding of the Contract Auditor in each case must be that the initial decision to *admit* the patient to the IRF was not reasonable. In order to make this decision, the Contract Auditor must focus on the facts in existence at the time of admission. Notwithstanding this requirement, the Contract Auditor frequently relies on the patient's post-admission condition, which frequently had improved, to justify a determination that the patient should not have been admitted to the IRF in the first instance. The result: in addition to focusing on the wrong information, Saint Francis is penalized for the successful treatment of its patients.
7. **Failure to Consider Positive Patient Progress and Outcomes.** While the Contract Auditor may not determine the propriety of the decision to *admit* a patient based on subsequent events, such events may be used by Saint Francis to demonstrate that the initial decision to admit was, in fact, appropriate. By way of example, the ability of the patients at issue to tolerate intensive rehabilitation therapy supports their admission to an IRF.

With respect to the 30 High Severity Claims — 9 of which Contract Auditor concluded were incorrectly coded — Saint Francis believes that 5 of these claims were correctly coded, and that multiple errors were made in determining the reimbursement and, therefore, overpayment amounts associated with these claims. Finally, with respect to both the IRF and High Severity Claims (1) the relevant statutes, regulations, and subregulatory guidance do not permit extrapolation under the circumstances presented here, and (2) the results of the Audit are not probative of whether Saint Francis incorrectly coded IRF or High Severity Claims outside the Audit Period and, as such, do not create any duty on the part of Saint Francis to review such claims under the overpayment statute.

Section III **Response to Contract Auditor Review of IRF Claims**

As noted above, the Draft Report concludes that Saint Francis “incorrectly billed Medicare Part A for beneficiary stays that did not meet the Medicare criteria for acute inpatient rehabilitation” with respect to 44 of the 70 IRF Claims in the audit sample, resulting in alleged overpayments to Saint Francis totaling \$686,893. Each of the 44 IRF Claims at issue has been reviewed by Optum Executive Health Resources (“EHR”), a nationally-recognized, independent healthcare consultant specializing in forensic evaluations of hospital inpatient and outpatient medical records. Applying the relevant Medicare criteria for acute inpatient rehabilitation, EHR has determined that all 44 IRF Claims were correctly billed. EHR’s conclusions are set forth on claim-by-claim basis in Appendix A, which is incorporated herein by reference. Set forth below is some background information, a summary of what Saint Francis believes to have been the more systemic errors relating to the IRF Claims, and a discussion of the reasons Saint Francis believes that the Extrapolation and 60-Day Rule Recommendations should be removed from the Draft Report.

A. All 44 IRF Claims Satisfied Relevant Medicare Criteria

The Medicare 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.⁵ IRF care is considered to be reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act (“SSA”) only if the patient meets all of the requirements set forth in 42 C.F.R. § 412.622(a)(3)-(5). Specifically, in order for an IRF claim to be considered reasonable and necessary, there must be a reasonable expectation — at the time of the patient’s admission to the IRF — that the patient:

- requires the active and ongoing therapeutic intervention of multiple therapy disciplines, one of which must be physical or occupational therapy,
- requires and can reasonably be expected to actively participate in, and benefit from, an intensive rehabilitation therapy program,⁶
- is stable enough to participate actively in the intensive rehabilitation therapy program described above, and
- requires physician supervision by a rehabilitation physician, defined as a licensed physician with specialized training and experience in inpatient rehabilitation.⁷

This reasonable expectation, in turn, must be documented in the patient’s file.⁸

As reflected in [Appendix A](#), all required Medicare documentation was complete and present with respect to each of the 44 IRF Claims. This documentation, in turn, establishes that each patient needed coordinated care by specialized nurses, specialized physicians, therapists, social workers, and nutritionists (i.e., care that generally is not provided in non-IRF settings). The documentation also establishes that each patient received and benefitted from an interdisciplinary team approach to care. For example, the documentation in each patient’s medical record of weekly interdisciplinary team meetings⁹ establishes that the patient received the interventions and therapy designed to help the

⁵ Medicare Benefit Policy Manual (“MBPM”) (CMS 100-02), ch. 1, § 110.

⁶ Under current industry standards, intensive rehabilitation therapy programs generally consist of at least three hours of therapy per day at least five days per week. In certain well-documented cases, this intensive rehabilitation therapy program might instead consist of at least 15 hours of intensive rehabilitation therapy within a seven consecutive day period, beginning with the date of admission to the IRF. Benefit from this intensive rehabilitation therapy program is demonstrated by measurable improvement that will be of practical value to the patient in improving the patient’s functional capacity or adaptation to impairments. The required therapy treatments must begin within 36 hours from midnight of the day of admission to the IRF.

⁷ The requirement for medical supervision means that the rehabilitation physician must conduct face-to-face visits with the patient at least 3 days per week throughout the patient’s stay in the IRF to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient’s capacity to benefit from the rehabilitation process. 42 C.F.R. § 412.622(a)(3).

⁸ 42 C.F.R. § 412.622(a)(4).

⁹ Id. § 412.622(a)(5).

patient (1) mobilize, (2) demonstrate improvement in the activities of daily living, (3) receive aggressive pain management, (4) improve nutrition, and (5) be assured that medical comorbidities do not interfere with therapy.

In addressing review standards for covered inpatient hospital services, the Medicare Benefit Policy Manual (“MBPM”) states that

[u]nder original Medicare, the Quality Improvement Organization (QIO), for each hospital is responsible for deciding, during review of inpatient admissions on a case-by-case basis, whether the admission was medically necessary. Medicare law authorizes the QIO to make these judgments, and the judgments are binding for purposes of Medicare coverage. In making these judgments, however, QIOs consider only the medical evidence [that] was available to the physician at the time an admission decision had to be made. They do not take into account other information (e.g., test results) which became available only after admission, except in cases where considering the post-admission information would support a finding that an admission was medically necessary.¹⁰

The MBPM goes on to clarify that “in order for IRF care to be considered reasonable and necessary, the documentation in the patient’s IRF medical record” — including the preadmission screening, post-admission physician evaluation, overall plan of care, and admission orders — “must demonstrate a reasonable expectation that the . . . criteria were met at the time of admission to the IRF.”¹¹

As demonstrated in [Appendix A](#), with respect to each of the 44 IRF Claims at issue, all the documentation and standards required by the Centers for Medicare & Medicaid Services (“CMS”) were present. In light of this, the Contract Auditor needed to make very specific findings, supported by facts contained in the medical record, to conclude that the patient was *not* appropriately admitted to the IRF. Instead, as discussed below, the Contract Auditor created and applied its own standard of review.

B. The Contract Auditor Applied the Wrong Standard of Review

The standard of review that the Contract Auditor applied is this:

However, there was no reason to think that an intensive rehabilitation therapy program would significantly impact the patient’s condition differently compared with therapy provided at a less intensive level. Her rehabilitation could have been provided at a lower level.

As detailed above, this is not the standard provided for in the relevant authorities, which (instead) is this: at the time of admission, the IRF must have a reasonable expectation that the patient (1) requires the active and ongoing intervention of multiple therapies, including physical or occupational therapy, (2) is sufficiently stable and able to actively participate and demonstrate measurable functional improvement in an intensive rehabilitation therapy program, and (3) requires supervision by a

¹⁰ MBPM, ch. 1, § 10 (rev. Mar. 10, 2017).

¹¹ MBPM, ch. 1, § 110 et seq.

rehabilitation physician to assess the patient medically and functionally and to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.

Plainly, the relevant authorities do not require a provider to determine whether the IRF stay will "significantly impact the patient's condition compared with therapy provided at a less intensive level." For example, nothing in the coverage criteria requires the IRF to determine whether the patient might recover as quickly in a skilled nursing facility setting. Instead, the provider simply focuses on whether the patient meets IRF criteria at the time of admission.¹² If so, the admission is appropriate.

Finally, we would note that while it is not uncommon for HHS-OIG and provider reviewers to disagree on the disposition of particular claims, it is highly unusual to find across-the-board disagreement with respect to 100 percent of the claims at issue. The results of this review raise significant concerns regarding the objectivity of the Contract Auditor and the conclusions reached in the Draft Report. In short, the disregard for (1) the comprehensive medical records furnished for each patient, (2) the assessments furnished by the treating physiatrist, and (3) the overall condition of, and treatment received by, the patients, coupled with the case review standards discussed above, makes each of the reviewer's findings clearly erroneous.

C. Extrapolation of the Results in the Draft Report Relating to the IRF Claims is Not Permitted by Law

As noted above, the Draft Report proposes that the results of the Audit be extrapolated to all 610 of the IRF Claims in the sample frame from which the 70-claim sample was drawn. Saint Francis believes that extrapolation is not appropriate here for two reasons. First, the Medicare Program Integrity Manual ("PIM") requires the selection of "a sample whereby each element in the sample has an equal opportunity of being selected and is thus representative of the original universe" ("Equal Opportunity Rule").¹³ Assume, for example, that HHS-OIG audits Hospital A to determine whether it complied in 2016 with the relevant Medicare coverage and billing requirements relating to Procedure X. The total universe of claims falling into this category is 500. Instead of reviewing all 500 claims, HHS-OIG decides to select 30 of the 500 claims and then extrapolate the results of its review over the entire 500-claim universe. Before HHS-OIG can extrapolate, it must comply with the Equal Opportunity Rule. In other words, if the agency wants to extrapolate across all 500 of the claims in the universe, the 30-claim sample must be drawn from the 500-claim universe. The agency cannot, for example select the 30 claims from the 250 claims submitted between January and June 2016, but then extrapolate the results of that review over the 500 claims submitted between January and December 2016.

To satisfy the requirements of the Equal Opportunity Rule, the PIM contemplates a three-step process: (1) the identification of a defined "universe" of claims; (2) the removal from the universe of any claims that should not be part of the statistical study, resulting in the "sampling frame"; and (3) the

¹² The requirement that the IRF admission be judged at the time of admission is appropriate. Any other standard would make the IRF the guarantor of the patients' outcomes. Otherwise, auditors would be able to look at unsuccessful IRF stays and then retroactively deny the admission reasoning that the subsequent stay showed that the admission decision was incorrect. Instead, an auditor must show that there was **no reasonable expectation at the time of admission** that the criteria (that in and of themselves require a good deal of medical judgment) were or would be met.

¹³ The referenced section of PIM states that a "probability sample" shall always be used, and that "[e]ach sampling unit in each distinct possible sample" should have a known probability of selection and those probabilities "should all be greater than zero." See PIM § 8.4.2.

random selection of a statistically meaningful “sample” of claims from the sampling frame.¹⁴ According to the PIM, the two types of claims that routinely are in the universe but must be excluded from the sample frame (pursuant to Step 2 above) are denied claims (i.e., claims that were not paid in the first instance) and duplicative claims (i.e., claims that were part of a prior audit or review).¹⁵ Here, it would appear that HHS-OIG skipped Step 2, leading to a violation of the Equal Opportunity Rule with respect to the IRF Claims covered by the Draft Report.

- First, it is undisputed that at least two of the claims in the 610-claim universe had been previously reviewed in the course of another government claim review. Specifically, the two claims at issue — which, as a matter of statistical integrity, should have been removed from the sampling frame, but ended up being selected as part of the 70-claim sample — already had been reviewed by Saint Francis’s MAC and are currently under administrative appeal. The failure of HHS-OIG to remove these two duplicative claims (the “MAC Claims”) before the selection of the allegedly random sample violated the Equal Opportunity Rule.
- Second, in addition to tainting the 610-sampling frame, the failure to remove the duplicative MAC Claims tainted the 70-claim sample. In order for the 70-claim sample to comply with the Equal Opportunity Rule — and thus for the results of the Audit to be eligible for extrapolation across the 610-claim sample frame — each of the 610 claims in the sample frame needed to have an “equal opportunity of being selected” to be among the 70 claims in the sample. That was not the case here, however. Specifically, the MAC Claims did not have an “equal opportunity of being selected.” Among other things, this is evidenced by the fact that after having learned of their existence, HHS-OIG “removed” them from the 70-claim sample. As a result, HHS-OIG actually reviewed only 68 of the 610 claims in the original universe and sample frame (and not 70, as stated in the Draft Report).

In sum, from the start, two of the claims in the 610-sample frame had a zero percent chance of being selected for review by HHS-OIG because they already were under review by the MAC. Pursuant to the Equal Opportunity Rule, then, the 70-claim sample was not representative of the 610-claim sample frame and, consequently, the results of the review of the 70-claim sample cannot be extrapolated across the 610-claim sample frame.¹⁶ Nor, of course, can this problem be remedied simply by ignoring the two MAC Claims in the 70-claim sample. The other 68 claims remain tainted because pursuant to the Equal Opportunity Rule, any claims selected from a tainted sample frame are, by definition, also tainted.

In addition to violating the Equal Opportunity Rule, the SSA provides that “a Medicare contractor may not use extrapolation to determine overpayment amounts” unless “there is a sustained or high level of payment error,” or “documented educational intervention has failed to correct the

¹⁴ See PIM § 8.4.3.2.

¹⁵ Id.

¹⁶ We note that it is possible that there were other MAC (or other contractor) reviewed claims in the original universe of 610 claims.

payment error.”¹⁷ CMS has incorporated this standard in the PIM.¹⁸ This standard is not met with respect to the IRF Claims.

- **High Level of Payment Error.** As detailed above and in [Appendix A](#), Saint Francis believes that none of the 70 IRF Claims were miscoded. Assuming this is correct, the resulting payment error rate is zero, which plainly does not satisfy the “high level of payment error” standard.
- **Sustained Level of Payment Error.** Nor does the Draft Report evidence a “sustained level of payment error.” The Draft Report covers a single audit and a single audit period. This is not a case, for example, where a contractor has:
 - concluded that in 2013, 2014, 2015, and 2016, a hospital had payment error rates of 22, 23, 22, and 23 percent, respectively, with respect to a particular procedure (“Procedure X”),
 - concluded that in 2017, the hospital had a payment error rate of 22 percent with respect to Procedure X, and
 - decided to extrapolate the 2017 audit results on the ground that the hospital had a sustained payment error rate — of 22, 23, 22, 23, and 22 percent over the course of five consecutive years — with respect to Procedure X.
- **Failed Educational Intervention.** Finally, we are not aware of any “documented educational intervention” occurring at Saint Francis prior to the Audit and, as such, the final ground for extrapolation — a determination that a “documented educational intervention has failed to correct the payment error” — is not supported here.

For both of these reasons then — the Audit violates the Equal Opportunity Rule and does not meet the conditions for extrapolation set forth in the SSA — Saint Francis respectfully requests that HHS-OIG remove the Extrapolation Recommendation from the Draft Report.

D. Using a Negligence-Based Constructive Knowledge Test, Saint Francis Has No Duty Under the Overpayment Statute to Review IRF Claims Outside the Audit Period

The Draft Report recommends that, “in accordance with the 60-day rule,” Saint Francis “exercise reasonable diligence to identify and return” any overpayments relating to IRF Claims that may have been made outside the Audit Period. In pertinent part, the statute governing the reporting and returning of overpayments provides that “[i]f a person has received an overpayment, the person shall . . . report and return the overpayment . . . by . . . the date which is 60 days after the date on which the overpayment was identified” (“Overpayment Statute”).¹⁹

¹⁷ 42 U.S.C. § 1395ddd(f)(3); see *Gentiva Healthcare Corp. v. Sebelius*, 723 F.3 292 (D.C. Cir. 2013) (ruling that a Section 1395ddd(f)(3) determination could be made by the Secretary or her designee).

¹⁸ Medicare Program Integrity Manual, Pub. 100-08, ch. 8, sec. 8.4.1.2 (rev. 778, Mar. 16, 2018).

¹⁹ 42 U.S.C. § 1320a-7k(d).

Although the Overpayment Statute does not define the term “identified,” the overpayment regulations governing the Medicare fee-for-service program (“FFS Regulations”) provide that “[a] person has identified an overpayment” in either of two situations.

- First, an overpayment is identified “when the person has . . . determined that the person has received an overpayment and quantified the amount of the overpayment” (“Actual Knowledge Test”).²⁰
- Second, an overpayment is identified “when the person . . . should have through the exercise of reasonable diligence . . . determined that the person has received an overpayment and quantified the amount of the overpayment. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment” (“Constructive Knowledge Test”).²¹

For purposes of the Constructive Knowledge Test, the FFS Regulations do not define the term “reasonable diligence.” In the preamble to the FFS Regulations, however, CMS does discuss some aspects of “reasonable diligence.” In a nutshell, the agency’s position appears to be this: (1) if a provider receives “credible information,” (2) of a “potential overpayment,” (3) then the provider has a “duty to make a reasonable inquiry to determine whether an overpayment exists.”²²

For the reasons set forth below, Saint Francis does not believe that the Draft Report constitutes “credible information” of “potential overpayments” outside the Audit Period relating to IRF Claims. As a threshold matter, Saint Francis believes that the payment error rate associated with the IRF Claims is zero. Plainly, this does not constitute credible information of potential overpayments outside the Audit Period with respect to the IRF Claims.

Moreover, even if the payment error rate was greater than zero, there is no reason to believe that such errors would have been the result of any systemic or programmatic issues or errors. To the contrary, Saint Francis has a highly qualified IRF staff that receives regular feedback on their performance, as well as updates on current regulations and sub-regulatory guidance. In addition, Saint Francis utilizes “best of breed” software designed specifically for the IRF setting. The software utilizes a template charting format, which includes key elements within each document that must be satisfied before the template can be completed and that incorporates hard stops for regulatory compliance. In addition, where timeframe-driven requirements are applicable, the software provides alerts to ensure that practitioner signatures are obtained in a timely manner.

Finally, throughout the Audit Period, Saint Francis conducted a preadmission screening assessment to evaluate each patient’s need for and ability to tolerate an intensive rehabilitation program and to determine if the expected functional gains would be sufficient to warrant an IRF level of care. Saint Francis also required that a rehabilitation physician review and approve the assessment and the patient’s admission both before and within 48 hours of her or his admission. In addition, Saint Francis reviewed documentation to determine whether (1) the individualized overall plan of care for the patient was completed within four days of admission, (2) the rehabilitation physician was completing

²⁰ 42 C.F.R. § 401.305(a)(2).

²¹ *Id.*

²² *See, e.g.*, 81 Fed. Reg. 7654, 7661 (Feb. 12, 2016).

the face-to-face visit requirements, (3) the patients were receiving the required minutes of therapy each week, and (4) interdisciplinary team conferences were being held weekly.

In sum, Saint Francis believes that it had a robust IRF compliance program in place during the Audit Period; as a result of this program, all of the IRF Claims complied with relevant Medicare coverage, coding, and billing rules; as a result, the Draft Report does not provide credible information of potential overpayments either in or outside the Audit Period; and, as a result, HHS-OIG should remove the 60-Day Rule Recommendation from the Draft Report.

E. Using a Reckless Disregard/Deliberate Indifference-Based Constructive Knowledge Test, Saint Francis Has No Duty Under the Overpayment Statute to Review IRF Claims Outside the Audit Period

Finally, substantial legal arguments support the proposition that the Constructive Knowledge Test set forth in the FFS Regulations is no longer good law. In addition to the FFS Regulations, CMS has promulgated regulations implementing the Overpayment Statute with respect to Parts C and D of the Medicare Program (“MA Regulations”).²³ In all respects material to the Draft Report, the MA and FFS Regulations are identical.

Recently, in UnitedHealthcare Insurance Co. v. Azar (“United”), the plaintiff challenged the MA Regulations on the ground that the Constructive Knowledge Test set forth therein “unlawfully imposes a negligence standard on Medicare Advantage insurers to identify and report ‘overpayments,’ which is inconsistent with the standards of the False Claims Act to which it would otherwise align enforcement.”²⁴ The district court agreed, reasoning as follows:

- The MA Regulations provide that an MA organization has “identified” an overpayment when the MA organization has determined, “or should have determined through the exercise of reasonable diligence,” that the MA organization has received an overpayment.
- “In contrast, the False Claims Act — which the ACA refers to for enforcement... imposes liability for erroneous (‘false’) claims for payment submitted to the government that are submitted ‘knowingly.’”
- “‘Knowingly’ is “a term of art defined in the [False Claims Act] to include false information about which a person ‘has actual knowledge,’ ‘acts in deliberate ignorance of the truth or falsity of the information,’ or ‘acts in reckless disregard of the truth or falsity of the information.’”
- “In summary, the FCA and the ACA require actual knowledge, deliberate ignorance, or reckless disregard before liability can be found.”
- The standard in the FCA or the ACA “is certainly not the standard in the [MA Regulations], however much CMS might want to make it so.”
- “Congress clearly had no intention to turn the [False Claims Act], a law designed to punish and deter fraud, into a vehicle for either ‘punish[ing] honest mistakes or incorrect claims

²³ 42 C.F.R. §§ 422.326 (Part C) and 423.360 (Part D).

²⁴ No. 16-157, 2018 WL 4275991, at *13 (D.D.C. Sept. 7, 2018)

submitted through mere negligence’ or imposing ‘a burdensome obligation’ ... rather than a ‘limited duty to inquire.’” United States v. Sci. Applications Int’l Corp., 626 F.3d 1257, 1274-75 (D.C. Cir. 2010) (quoting S. Rep. No. 99-345, at 6, 19 (1986)).”

- “With these proscriptions in mind, the [MA Regulations extend] far beyond the False Claims Act and, by extension, the Affordable Care Act. Not being Congress, CMS has no legislative authority to apply more stringent standards to impose FCA consequences through regulation.”²⁵

The reasoning behind the United court’s decision to vacate CMS’ negligence-based Constructive Knowledge Test in the context of the MA Regulations applies with equal force to the identical negligence-based Constructive Knowledge Test in the FFS Regulations. Simply put, United appears to stand (at a minimum) for the following proposition: if the failure by a hospital to determine that it has received an overpayment is the result of “negligence” (i.e., a failure to exercise “reasonable diligence”), and not the result of “deliberate ignorance” or “reckless disregard,” the hospital has not “identified” an overpayment for purposes of the Overpayment Statute. If this is correct, even were we to assume — solely for the sake of argument — that notwithstanding the extremely low payment error rate and particular nature of the errors at issue, the decision by Saint Francis not to review IRF Claims outside the Audit Period would constitute “negligence,” it certainly would not rise to the level of “deliberate ignorance” or “reckless disregard” of the truth.

Finally, in addition to all of the reasons set forth above, the 60-Day Rule Recommendation should be removed from the Draft Report because it is premature. In response to CMS’s proposed FFS Regulations, several commenters asked HHS-OIG for guidance as to the applicability of the report and return rule where — as here — there is a dispute between the provider and government as to whether a particular claim was or was not incorrectly coded and, therefore, whether the claim did or did not result in an overpayment. CMS provided the requested guidance, and it is quite clear: “If the provider appeals the contractor identified overpayment” — as is the case here — “the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process.”²⁶

For all of the reasons set forth above, then, Saint Francis requests that the HHS-OIG remove the 60-Day Rule Recommendation from the Draft Report.

F. Conclusion with Respect to IRF Claims

Saint Francis submitted 610 IRF Claims during the Audit Period. HHS-OIG reviewed 68 of these Claims, concluding that 44 were incorrectly coded. For the reasons set forth in Appendix A, Saint Francis believes that the 44 IRF Claims at issue were correctly coded, resulting in a payment error rate of 0.00 percent. Saint Francis further believes that under the standard established by Congress in the SSA, and in light of the fact that the IRF Claim sample violated the Equal Opportunity Rule, extrapolating any error rate across the 610-claim universe covered by the Audit Period is not permissible. Saint Francis believes that whether the correct Constructive Knowledge Test is as set forth in the current FFS Regulations or as articulated by the court in United, neither the 0.00 percent error rate, nor any other information

²⁵ Id.

²⁶ 81 Fed. Reg. 7654, 7667 (Feb. 12, 2016).

provided to Saint Francis, triggers a legal obligation on the part of Saint Francis to review IRF Claims outside the Audit Period. For all of these reasons, Saint Francis respectfully requests that HHS-OIG remove the Extrapolation and 60-Day Rule Recommendations from the Draft Report and recommend the recovery of \$0.00 relating to the IRF Claims.

Section IV
Response to HHS-OIG Auditor Review of High Severity Claims

As noted above, the Draft Report concludes that 9 of the 30 High Severity Claims “were incorrectly coded, resulting in allegedly incorrect DRG payments to [Saint Francis]” totaling \$23,289.

A. The Contract Auditor’s Findings with Respect to 5 Claims and Its Overpayment Calculations with Respect to All 9 Claims Are Incorrect

As a threshold matter, even assuming all 9 of the claims at issue were incorrectly coded, the Contract Auditor incorrectly calculated the resulting overpayment amount to be \$23,289. As reflected in Table 1 below, the actual overpayment amount associated with the 9 claims is \$14,709.64.²⁷ Further, although Saint Francis agrees that 4 of the 9 High Severity Claims (B08, B12, B27, and B28) were incorrectly coded, Saint Francis believes that the remaining 5 claims (B05, B09, B16, B25, and B30) were correctly coded in the first instance. With respect to the 5 claims that Saint Francis believes were correctly coded, the clinical support for the hospital’s position is set forth in Appendix A, which is incorporated herein by this reference.

In light of the above, Saint Francis respectfully requests that HHS-OIG revise the Draft Report to (1) reflect the fact that only 4 of the 9 High Severity Claims (B08, B12, B27, and B28) were incorrectly coded, and (2) revise the payment and associated overpayment data in accordance with Table 1 below to reflect a total overpayment amount of \$5,565.71.

²⁷ Table 1 shows the original DRG assignment and associated reimbursement data. It also shows HHS-OIG’s proposed DRG assignment and associated reimbursement for all 9 claims. Finally, the table reflects the corrected DRG assignment with which Saint Francis agrees and shows the reimbursement data Saint Francis would receive based on the corrected DRG assignment. HHS-OIG’s overpayment calculations for the 9 claims overstate the alleged overpayment by \$8,579.07. We also note, in the interests of full transparency, that Saint Francis should receive less reimbursement for claim B08 than suggested by HHS-OIG, resulting in a higher overpayment for that claim.

Table 1

Sample #	Original		HHS-OIG Adjusted			Saint Francis Adjusted		Potential Overpayment	Conceded Claims Overpayment
	DRG	Pmt Amt	DRG	Pmt Amt	Overpayment	DRG	Pmt Amt		
B05	199	\$8,158.25	201	\$2,848.54	\$5,309.71	201	\$4,343.38	\$3,814.87	
B08	194	\$5,588.68	195	\$4,160.99	\$1,427.69	195	\$4,082.47	\$1,506.21	\$1,506.21
B09	600	\$5,401.10	601	\$3,812.25	\$1,588.85	601	\$4,015.58	\$1,385.52	
B12	194	\$4,692.74	195	\$3,343.98	\$1,348.76	195	\$4,199.86	\$492.88	\$492.88
B16	442	\$3,892.50	443	\$2,417.42	\$1,475.08	443	\$3,865.57	\$26.93	
B25	638	\$4,813.35	639	\$3,630.46	\$1,182.89	639	\$3,516.81	\$1,296.54	
B27	067	\$6,502.39	066	\$2,963.65	\$3,538.74	66	\$4,473.31	\$2,029.08	\$2,029.08
B28	643	\$5,698.83	645	\$2,995.46	\$2,703.37	645	\$4,161.29	\$1,537.54	\$1,537.54
B30	330	\$12,359.89	331	\$7,646.27	\$4,713.62	331	\$9,739.82	\$2,620.07	
Total					\$23,288.71			\$14,709.64	\$5,565.71

B. Extrapolation of the Results in the Draft Report Relating to the High Severity Claims is Not Permitted by Law

As noted above, the Draft Report proposes that the results of the Audit be extrapolated to all 802 of the High Severity Claims in the sample frame from which the 30-claim sample was drawn. Largely for the same reasons set forth with respect to the IRF Claims in Section III.C. above, the standard for extrapolation set forth in the SSA is not met with respect to the High Severity Claims.

- **High Level of Payment Error.** For the reasons set forth above, Saint Francis believes that just 4 of the 30 High Severity Claims were incorrectly coded. Assuming this is correct, and using the figures set forth in Table 1 above, the resulting payment error rate is 2.32 percent, which cannot reasonably be characterized as a “high level of payment error.”²⁸
- **Sustained Level of Payment Error.** The Draft Report does not evidence a “sustained level of payment error.” Once again, the Draft Report covers a single audit and a single audit period.
- **Failed Educational Intervention.** Finally, we are not aware of any “documented educational intervention” occurring at Saint Francis prior to the Audit and, as such, the final ground for extrapolation — a determination that a “documented educational intervention has failed to correct the payment error” — is not supported here.

In sum, because there is no evidence in the Draft Report of (1) a “high level of payment error,” (2) a “sustained level of payment error,” or (3) “documented educational intervention” that “failed to correct” a “payment error,” the government “may not use extrapolation to determine overpayment

²⁸ Indeed, even for purposes of corporate integrity agreement (“CIA”) compliance, where a claims review results in a financial error rate of less than five percent, HHS-OIG does not require extrapolation. See HHS-OIG Website, Corporate Integrity Agreement FAQ, <https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp>. Note that the 2.32 percent figure was calculated as follows: the difference in Medicare payment associated with the 4 claims containing errors (\$5,565.71) divided by the total Medicare reimbursement received in connection with the 30 High Severity Claims (\$210,067.41). Further note that Saint Francis has not undertaken a review to determine whether coding errors may have resulted in any underpayments, which would further reduce (or even negate) the 2.32 percent payment error rate.

amounts.” As such, Saint Francis respectfully requests that HHS-OIG remove the Extrapolation Recommendation from the Draft Report and limit its recommendation to the actual overpayment amount set forth in Section IV.A. above (i.e., \$5,565.71).

C. Using a Negligence-Based Constructive Knowledge Test, Saint Francis Has No Duty Under the Overpayment Statute to Review High Severity Claims Outside the Audit Period

As noted above, the Draft Report recommends that “in accordance with the 60-day rule,” Saint Francis “exercise reasonable diligence to identify and return” any overpayments that may have been made outside the Audit Period.²⁹ Applying the test set forth in Section III.D. above, for the reasons set forth below, the findings in the Draft Report do not constitute “credible information” of potential overpayments relating to High Severity Claims submitted outside the Audit Period. As a threshold matter, Saint Francis believes the payment error rate with respect to the 30-claim sample at issue is extremely low (2.32 percent).³⁰ In addition, with respect to the 4 High Severity Claims that Saint Francis agrees were incorrectly coded (B08, B12, B27, and B28), the mistakes at issue were not the result of any “systemic” or “programmatic” issues or errors. To the contrary, during the Audit Period:

- all personnel responsible for performing, supervising, and/or monitoring the coding of inpatient services had access to the 3M Encoder, AHA Coding Clinic, and other authoritative references in support of code selection and the application of coding guidelines; and
- all Hospital coding personnel (1) were required to participate in annual coding continuing education, (2) received one-on-one attention in connection with any identified coding errors, and (3) were subject to performance improvement plans (including expanded pre-bill reviews), where results were consistently below accepted standards.

Notwithstanding these robust coding education and quality assurance programs, because humans are fallible — and because High Severity Claim coding is both subjective and otherwise complicated — one-off errors by individual coders can occur. The 4 claims at issue here — each of which was coded by a different individual — are excellent examples of this:

- **Claim B08.** Although the principal diagnosis of pneumonia was substantiated in the medical record, the coder incorrectly assigned a secondary diagnosis of chronic obstructive

²⁹ Draft Report at 6.

³⁰ This is well below the 5 percent benchmark HHS-OIG itself utilizes in determining whether a provider is required to do any further audit work under corporate integrity agreements (“CIAs”). See HHS-OIG “Summary of New CIA Claims Review Procedures” (November 20, 2001) (“If the net financial error rate of discovery sample is below 5% (the reportable error rate), provider is not required to do any further audit work under the CIA for that year. Results are reported to HHS-OIG and identified overpayments (if any) are refunded in accordance with payor policies”) <https://oig.hhs.gov/fraud/docs/openletters/openletterssumm111901.pdf> (last accessed Oct. 23, 2018); see also HHS-OIG Corporate Integrity Agreement FAQ, CIA Claims Reviews, <https://oig.hhs.gov/faqs/corporate-integrity-agreements-faq.asp> (“Note: If conducting a discovery sample, a full sample size is only required if the net financial error rate of the discovery sample equals or exceeds 5 percent.”) (last accessed Oct. 23, 2018).

bronchitis based on a listing of differential diagnoses in the emergency room note. The coder should have included a secondary diagnosis of chronic obstructive pulmonary disease.

- **Claim B12.** The coder incorrectly assigned a secondary diagnosis of hemiplegia based on medical record documentation of the patient's history of right-sided weakness of extremities, but there was no indication of current weakness.
- **Claim B27.** The coder inadvertently assigned vertebral artery stenosis as a principal diagnosis. However, it was the cerebrovascular accident ("CVA"), and not the vertebral artery stenosis, that occasioned the patient to be admitted. As such, the CVA should have been coded as the principal diagnosis with the vertebral artery stenosis as a secondary condition.
- **Claim B28.** The coder inadvertently assigned a secondary diagnosis of pneumonia based on documentation of a problem list carried over from a previous visit. However this was not assessed or treated in this visit and should not have been included.

In sum, given the extremely low underlying payment error rate (2.32 percent), coupled with the particular nature of the errors at issue, we do not believe that the discovery of 4 coding errors over a 740-day period constitutes "credible information" of the existence of a "potential overpayment" relating to High Severity Claims outside the Audit Period. As a result, the current FFS Regulations impose no duty on Saint Francis to review High Severity Claims outside the Audit Period. Accordingly, Saint Francis respectfully requests that HHS-OIG remove the 60-Day Rule Recommendation from the Draft Report.

D. Using a Reckless Disregard/Deliberate Indifference-Based Constructive Knowledge Test, Saint Francis Has No Duty Under the Overpayment Statute to Review High Severity Claims Outside the Audit Period

As discussed in Section III.E. above, United appears to stand (at a minimum) for the following proposition: if the failure by a hospital to determine that it has received an overpayment is the result of "negligence" (i.e., a failure to exercise "reasonable diligence"), and not the result of "deliberate ignorance" or "reckless disregard," the hospital has not "identified" an overpayment for purposes of the Overpayment Statute. If this is correct, even were we to assume — solely for the sake of argument — that notwithstanding the extremely low payment error rate and particular nature of the errors at issue, the decision by Saint Francis not to review High Severity Claims outside the Audit Period would constitute "negligence," it certainly would not rise to the level of "deliberate ignorance" or "reckless disregard" of the truth. For this additional reason, then, Saint Francis requests that the HHS-OIG remove the 60-Day Rule Recommendation from the Draft Report.

E. Conclusion with Respect to the High Severity Claims

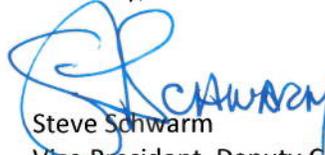
Saint Francis submitted 802 High Severity Claims during the Audit Period. HHS-OIG reviewed 30 of these Claims, concluding that 9 were incorrectly coded. For the reasons set forth in Table 1 and Appendix B, Saint Francis has provided evidence that 5 of the 9 claims at issue were correctly coded, resulting in a payment error rate of just 2.32 percent. Under the standard established by Congress in the SSA, extrapolating this error rate across the 802-claim sample frame covered by the Audit Period is not permissible. Finally, whether the correct Constructive Knowledge Test is as set forth in the current FFS Regulations or as articulated by the court in United, neither the 2.32 percent error rate nor any other information provided to Saint Francis triggers an obligation to review High Severity Claims outside

the Audit Period. For all of these reasons, Saint Francis requests that HHS-OIG remove the Extrapolation and 60-Day Rule Recommendations from the Draft Report and recommend only the recovery of \$4,882, reflecting the accurate overpayment amount relating to the 4 High Severity Claims that both Saint Francis and HHS-OIG agree were incorrectly coded.

* * *

On behalf of Saint Francis, we thank you in advance for your consideration of our position and stated concerns. We will make ourselves available to you in the event that you have any questions or require further information.

Sincerely,



Steve Schwarm
Vice President, Deputy Counsel ~~GENERAL COUNSEL~~
SCL Health