UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
AUDIT AND ADVISORY SERVICES

UCSF Health Clinical Laboratory Billing
Project #16-058

June 2016
June 30, 2016

DANIEL WANDRES
VP, Clinical Services
UCSF Health

SUBJECT: Clinical Laboratory Review

As a planned internal audit for Fiscal Year 2016, Audit and Advisory Services (“AAS”) conducted a review of UCSF Health’s Clinical Laboratory’s billing processes and controls. Our services were performed in accordance with the applicable International Standards for the Professional Practice of Internal Auditing as prescribed by the Institute of Internal Auditors (the “IIA Standards”).

Our review was completed and the preliminary draft report was provided to department management in June 2016. Management provided us with their final comments and responses to our observations in June 2016. The observations and corrective actions have been discussed and agreed upon with department management and it is management’s responsibility to implement the corrective actions stated in the report. In accordance with the University of California audit policy, AAS will periodically follow up to confirm that the agreed upon management corrective actions are completed within the dates specified in the final report.

This report is intended solely for the information and internal use of UCSF management and the Ethics, Compliance and Audit Board, and is not intended to be and should not be used by any other person or entity.

Sincerely,

Irene McGlynn
Director
UCSF Audit and Advisory Services
EXECUTIVE SUMMARY

I. BACKGROUND

As a planned audit for Fiscal Year 2016, Audit and Advisory Services (AAS) engaged Aegis Compliance & Ethics Center, LLP to perform a laboratory billing compliance review for the UCSF Health clinical laboratories.

The Department of Health & Human Services’ Office of Inspector General (OIG) issued Compliance Program Guidance for clinical laboratories in 1998 (63 Federal Register 45076; August 24, 1998) to provide clinical laboratories with specific areas of risk and recommendations to mitigate that risk within the framework of an effective compliance program, including laboratory-specific risks around which an organization should structure its controls. The OIG guidance pays particular attention to risks that could result in the submission of improper claims to federal health care programs, namely medical necessity, billing, and reliance on standing orders. Non-compliance with this guidance could result in inappropriate billing leading to required repayments.

In Fiscal Year 2015 UCSF Clinical Laboratory generated $772.3M in gross revenue and incurred expenses amounting to $111.4M.

II. AUDIT PURPOSE AND SCOPE

The purpose of this review was to analyze UCSF clinical laboratory’s compliance with the OIG’s Compliance Guidance for Clinical Laboratories and adherence with federal regulations aimed at preventing inappropriate billing to federal health care programs.

The scope of the review covered transactions and activities for 2015 at UCSF Health clinical laboratories.

Procedures performed as part of the review included reviewing the charge capture process, ordering, appropriate coding (including CPT, ICD9, and ICD10), policies and procedures, Advance Beneficiary Notices (ABN), medical necessity, reimbursement, and provider involvement.

Work performed was limited to the specific activities and procedures described above. As such, this report is not intended to, nor can it be relied upon to provide an assessment of compliance beyond those areas specifically reviewed. No remittance advices were reviewed with respect of identifying actual payments. Fieldwork was completed in May 2016.

III. SUMMARY

Based on work performed, UCSF laboratory has an effective compliance program in place demonstrated through providing notice to providers annually that includes Local Coverage determination updates, National Coverage Decisions updates, OIG Compliance Guidance for Laboratories, the Medicare Laboratory Fee schedule and the UCSF reflex test policy. Additionally, the Charge Description Master (CDM) is reviewed annually for new codes addition or inactivation, best practices are followed for non-use of custom panels, and controls are in place to support effective charge capture and prevent billing for non-performed or non-resulted tests or calculations.
Opportunities for improvement exist in the areas of documenting diagnoses, ordering, use of modifiers and policies and procedures surrounding ABNs. The specific observations from this review are listed below.

Medical Necessity

- Diagnosis codes were not present on orders that interface from the Sunquest system to APeX
- Paper requisitions entered in Sunquest and that flow into APeX are noted as signed by the provider without signatures being present
- ABNs may not always be obtained when required

Billing

- Modifiers may be used inappropriately
### A. Medical Necessity

<table>
<thead>
<tr>
<th>No.</th>
<th>Observation</th>
<th>Risk/Effect</th>
<th>Recommendation</th>
<th>MCA</th>
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<tbody>
<tr>
<td>1</td>
<td><strong>Diagnosis codes were not always present on orders.</strong></td>
<td>The medical record may not be complete.</td>
<td>• All pertinent information, including ICD-10 codes, should be interfaced from SunQuest to APeX on the “unsolicited/electronic order” as a best practice.</td>
<td>By July 31, 2016 Clinical Laboratory management will submit APeX/ Epic interface change request to change title of record</td>
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<td>While all charges had a diagnosis code present, 6 of 37 accounts reviewed did not have a diagnosis on the APeX “unsolicited/electronic order”.</td>
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<td>These accounts were ordered from a paper requisition that were then scribed into the Laboratory Sunquest system by the Laboratory staff. According to the Laboratory Director, the Sunquest information is transferred to APeX via an interface. This interface creates an “unsolicited/electronic order”. When the information is transferred to APeX, the diagnosis is not reflected on the “unsolicited/electronic” order; however, it is posted in the Epic Hospital Billing record.</td>
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<td>2</td>
<td><strong>Paper requisitions were entered as signed without signatures being present.</strong></td>
<td>The medical record may not be complete.</td>
<td>• For those paper requisitions where the ordering information is transferred to APeX, the “electronically signed by” be removed from the “unsolicited order” if in fact, the physician never actually signed the electronic requisition in APeX.</td>
<td>By July 31, 2106 Clinical Laboratory management will submit APeX/ Epic interface request to change title of record</td>
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<td>Upon transference of data from Sunquest to APeX for paper requisitions to the “unsolicited/electronic order”, it appears that the ordering physician has “electronically signed” the requisition in APeX when in actuality the physician had not signed it. According to the laboratory staff, the physicians who ordered via paper requisitions either chose not to enter into APeX or do not have access to APeX.</td>
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<td>Per Centers for Medicare &amp; Medicaid Services (CMS) guidelines services must be supported by an order service that must be authenticated by the ordering practitioner.</td>
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<td>3</td>
<td><strong>ABNs may not always be obtained when required.</strong></td>
<td>Possible inappropriate billing may occur. Write-offs may also occur due to no ABN being obtained.</td>
<td>• Lab ABN policy should be revised to reflect current practice.</td>
<td>a) By July 31, 2106 Clinical Laboratory management will edit current policy and route for approval</td>
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<td>Through various interviews, it was noted that the laboratory does not obtain Advance Beneficiary Notices (ABNs) for walk-ins or for outpatients as the UCSF physicians are responsible for the ABN process in APeX in the clinics. The laboratory obtained ABNs prior to the implementation of APeX in 2012.</td>
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### B. Billing

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</table>
| 1   | **Modifiers may be used inappropriately.** | Possible inappropriate billing may occur as well as improper payments may be received. | • Modifiers -59 or -91 should not be hard coded into the CDM and documentation should be utilized to support the usage of the modifier.  
• Review CPT code 87327 for possible replacement of 87899. | a) By July 31, 2016 Clinical Laboratory management will request modifier review by Patient Financial Services  
b) By July 31, 2016 Clinical Laboratory management will request review of CPT by Finance/Reimbursement Team |

Per current Lab policy, ABNs are to be obtained from Medicare patients if the test is unlikely to be reimbursed by CMS.

According to CMS guidelines, laboratories cannot bill a Medicare beneficiary for a lab test unless it notifies the patient in writing that Medicare is not going to pay for the test.

B) By August 31, 2016 Clinical Laboratory management will develop a process to resume obtaining ABNs for walk-ins.

Modifiers may be used inappropriately.

It was noted on CPT code, 87899, cryptococcal antigen modifier -59 has been hard coded into the charge master. CPT Code 87899 is an unlisted code. A better-fit code of 87327 may be considered.

According to CMS, Modifier -59 Article, this modifier is an important NCCI associated modifier that is often misused creating improper payments.

Modifiers -59 or -91 should not be hard coded into the CDM and documentation should be utilized to support the usage of the modifier.

Review CPT code 87327 for possible replacement of 87899.