DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

7500 Security Boulevard, Mail Stop N1-19-21

Baltimore, Maryland 21244-1850

**Notice of Draft Findings**

Date of Notice: **FULLDATE**

CONTACTNAME

JOBTITLE

CENAME

ADDRESS1

ADDRESS2

CITY, ST ZIP

Re: Compliance Review Number **XXXXX**

Dear FIRSTNAME LASTNAME:

On **(month, day, year)**, the Department of Health and Human Services (HHS), National Standards Group (NSG) within the Centers for Medicare & Medicaid Services (CMS) completed the **<Covered Entity Name>** 20XX assessment.

The assessment included a review of transactions, code sets, unique identifiers, and operating rules. It was comprised of employing a validation tool to determine whether HIPAA transactions were compliant with the applicable 5010 ASC X12 standards and implementation guides. In addition, it included a manual review of companion guides and operating rule attestations, if applicable.

The assessment findings for **<Covered Entity Name>** reveals noncompliance in the following areas: transactions, code sets, unique identifiers, and operating rules. Refer to the enclosed Draft Violations Summary Report and corresponding validation tool report(s) that have been uploaded to the ASETT Covered Entity Portal. For assessment purposes, all unique error IDs and business messages with a “Normal” severity were reviewed. Please note, if envelope violations were present in the initial test of a transaction file (ISA/IEA – GS/GE), an alternative profile was used to bypass the envelope violations. This may have resulted in two corresponding validation tool report(s) for the same file when both contain “Normal” severity violations.

**<Covered Entity Name>** has the option of providing a response to each violation cited in the enclosed Draft Violations Summary Report. If **<Covered Entity Name>** disagrees with any violation, the basis for disagreement and all applicable references to support your position must be provided in writing. Your response must be received by this office no later than **(month, day, year)**, (10 business days). All responses will be taken into consideration and a NSG reply will be furnished in a subsequent Violations Summary Report. In addition, all activity and/or violation status changes will be reflected in a subsequent Violations Summary Report and uploaded to the ASETT Covered Entity Portal.

As a courtesy, we have provided a “Covered Entity Response” section in the enclosed Draft Violations Summary Report. If you choose to respond using the “Covered Entity Response” section, please append “Response” to the file name of this notice and upload it to the ASETT Covered Entity Portal by the response due date. Please refer to the *CMS Identity Management (IDM) System and Compliance Review Covered Entity Portal Access Quick Start User Guide* to review instructions for accessing the ASETT Covered Entity Portal.

Once received, NSG will review your response and provide a reply in a subsequent notice. You can expect the subsequent notice no later than **(month, day, year)**.

If you have any questions regarding this notice, please send an email to [HIPAACompliance@cms.hhs.gov](mailto:HIPAACompliance@cms.hhs.gov). Please include the compliance review number located at the top of this notice.

Sincerely,

**Michael Cimmino**

Director, National Standards Group

Office of Healthcare Experience and Interoperability

Centers for Medicare & Medicaid Services

Enclosure – Draft Violations Summary Report

**Draft – Violations Summary Report**

| **VIOLATION # 1** |
| --- |
| **Covered Entity File Name:** |
| **Validation Tool Reports** |
| **Consolidated Output File Name:** |
| **Individual Output File Name(s):** |
| **Violation Information** |
| **Violation Error ID:** |
| **Category:** <Select an option.> |
| **Violation Description:** |
| **Reference(s):** |
| **Warrant Corrective Action:** <Select an option.> |
| **Covered Entity Response** |
|  |
| **NSG Reply to Covered Entity (NSG Only)** |
|  |

| **VIOLATION # 2** |
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| **Covered Entity File Name:** |
| **Validation Tool Reports** |
| **Consolidated Output File Name:** |
| **Individual Output File Name(s):** |
| **Violation Information** |
| **Violation Error ID:** |
| **Category:** <Select an option.> |
| **Violation Description:** |
| **Reference(s):** |
| **Warrant Corrective Action:** <Select an option.> |
| **Covered Entity Response** |
|  |
| **NSG Reply to Covered Entity (NSG Only)** |
|  |

| **VIOLATION # 3** |
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| **Covered Entity File Name:** |
| **Validation Tool Reports** |
| **Consolidated Output File Name:** |
| **Individual Output File Name(s):** |
| **Violation Information** |
| **Violation Error ID:** |
| **Category:** <Select an option.> |
| **Violation Description:** |
| **Reference(s):** |
| **Warrant Corrective Action:** <Select an option.> |
| **Covered Entity Response** |
|  |
| **NSG Reply to Covered Entity (NSG Only)** |
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