American Bar Association

Technical Session Between the Centers for Medicare and Medicaid Services and the Joint Committee on Employee Benefits

May 7, 2007

The following notes are based upon the personal comments of the various individuals from the Centers for Medicare and Medicaid Services who attended a meeting with the representatives of the various sections comprising the Joint Committee on Employee Benefits from the American Bar Association. The comments were made by these individuals in their individual capacity and not as representatives of the Centers for Medicare and Medicaid Services. The comments do not represent the position of the Centers for Medicare and Medicaid Services or of any other government agency or office. None of the comments should be considered official guidance or the position of any agency.

This document has been prepared by private sector members of the American Bar Association's Joint Committee on Employee Benefits who were present at the meeting and reflects their description of the answers to the questions that were discussed at the meeting. This document has not been reviewed or cleared by the government individuals involved in the meeting.

HIPAA Electronic Transactions and Security Issues

1. HIPAA Security and Electronic Health Records.

Question #1: There has been much discussion in the trade press regarding electronic health records ("EHR"). Many of these discussions concern health care providers establishing and maintaining the EHR. Recently, health plans, specifically employer-sponsored group health plans, have started to provide EHRs for their employees and dependents who participate in the health plan. These EHRs are typically accessible from a secure website, using a specific user name and password. However, many commercial websites, such as banks and other financial institutions, are now using internet security protocols that are in addition to the traditional user name and password. These additional security protocols include pictures (referred to sometimes as site keys), and interactive questions (such as the name of the person's favorite pet).

1(a): Does a health plan need to provide additional levels of security beyond traditional usernames and passwords so that its EHRs comply with the HIPAA security rules? Would your answer change if a majority of all commercial websites used security protocols beyond the traditional username and password?

1(b): Is CMS developing any general standards or safe harbors under the HIPAA Security Rules that a health plan can follow for establishing and maintaining EHRs?

CMS Response:

The term, electronic health record or "EHR," is a term used to describe a medical record that is owned and controlled by a provider and is an individual's legal health record. The records that are being created now by employer-sponsored group health plans and other companies should be referred to as a personal health record or individual health record.

Currently, there is a health IT standards panel that is working on harmonizing the standards. However, under the HIPAA Security Rules there are required and addressable specifications. The health plan will need to determine what is appropriate for the level of risk. It will then need to have a written policy regarding the use of the website.

Further, the HHS semi-annual agenda listed a new regulation that will cover remote security guidance. This will formalize and expand upon the remote security guidance that was released in late 2006. The new regulation should be issued sometime in the Summer of 2007.

2. HIPAA Compliance Complaints.

Question #2: Can CMS provide statistics regarding complaints received under the HIPAA Security Rules and the HIPAA Electronic Transaction Rules? What have been

the top reasons for the complaints? How many complaints were against health plans versus health care providers? Has any enforcement action been taken with respect to any of the complaints?

CMS Response:

There have been approximately 600 CMS complaints since 2002 – 400 related to the electronic transaction rules and 200 related to the electronic security rules. Most complaints also include a HIPAA privacy component. Currently, approximately 90 complaints are open, of which 70 complaints also include a HIPAA privacy component.

Regarding the electronic security rules, the typical complaint alleges access to a person's PHI without permission. Some involve divorced spouses, while others involve laptops and disk drives that are lost or misplaced. The key question in these investigations are whether the safeguards were appropriate.

Regarding the electronic transaction rules, the level of these complaints has dropped off dramatically. However, the typical complaint alleges that the health plan won't accept a certain transaction, but usually this is because the health plan does not cover the service.

In addition, CMS is gearing up to accept NPI complaints.

3. HIPAA Transactions and Code Sets.

Question #3: Recently, it has been reported in the trade press that CMS has imposed corrective action plans on two health plans for violating the HIPAA electronic transaction and code set standards. Can CMS provide any details regarding whether the health plans were HMOs, insurers, or self-insured employer group health plans? If the plans involved self-insured employer group health plans, was the plan related to actions (or inactions) of a business associate? Further, can CMS provide any details regarding the specific HIPAA electronic transaction violations?

CMS Response:

The reporting of this event was overly-enthusiastic. Corrective action plans happen all the time and the event that was reported was not unique. Generally, people have been doing a good job complying with the electronic transaction and code sets.

<u>Medicare Part D</u>

4. Notice of Non-Creditable Coverage.

Question #4: Some employer group health plans cover only medical expenses, but exclude prescription drug coverage through plan design. For example, some employer

plans continue medical coverage for retirees, but not prescription drug coverage. Another example is that some employers sponsor a stand-alone health reimbursement arrangement ("HRA") for employees or retirees that reimburses medical, dental and vision expenses, but does not reimburse prescription drug expenses. If a health plan excludes prescription drug coverage as a matter of plan design, is the health plan required to send a notice of non-creditable coverage to each Part D eligible individual and is the sponsor required to include the health plan in its annual disclosure to CMS?

Proposed Answer #4: Page 2 of the February 15, 2007 creditable coverage guidance indicates that a disclosure notice must be provided to all Part D eligible individuals who are covered under, or who apply for, the entity's prescription drug coverage. This sentence indicates that if a health plan did not have any prescription drug coverage, then no notice is required. Therefore, a health plan that does not cover prescription drugs as a matter of plan design is not required to send a notice of non-creditable coverage to Part D eligible individuals and is not required to include such a plan in its annual disclosure to CMS.

CMS Response:

CMS agreed with the proposed answer.

5. Disclosure Notice for HRA.

Question #5: Assume Company A sponsors a health reimbursement arrangement ("HRA") for all of its employees. The HRA is limited to reimbursing co-pays, deductibles and co-insurance for medical and prescription drug expenses that are not covered by another medical or prescription drug plan (whether Company A's plan or another plan, such as a spouse's employer's plan, referred to as "Company B"). However, the covered services of the HRA are limited to those services covered by Company A's medical and prescription drug plan. For example, if a Company A employee is covered by Company A's prescription drug plan, any co-pay paid by such employee under Company A's prescription drug plan is automatically transmitted to the HRA's administrator and reimbursed (assuming the HRA has sufficient funds). However, if a Company A employee is covered by Company B's prescription drug plan, such employee can only obtain reimbursement for the co-pay from the HRA if the prescription drug is a drug that is covered by Company A's prescription drug plan. Assume further that Company A's prescription drug plan is creditable.

In this example, can Company A combine its prescription drug plan and the HRA and issue a single disclosure notice? (Assume that Company A has tested the HRA and the prescription drug plan together and that the two combined satisfy the requirements to be creditable coverage.) Or, alternatively, must Company A test the prescription drug plan and the HRA separately and issue two separate disclosure notices? (Assume that Company A has tested the HRA and the prescription drug plan separately and that

Company A would issue a creditable coverage disclosure notice for the prescription drug plan and a non-creditable coverage disclosure notice for the HRA.)

Proposed Answer #5: Under the CMS guidance for account-based health arrangements, a plan sponsor can integrate an HRA with another plan and issue a single, combined disclosure notice, if the plan is "an HDHP or other employer or union-sponsored group health plan (referred to as the "non-account" benefit)" and the individual participates in both the HRA and the non-account benefit. Therefore, if a Part D eligible individual participates in both the HRA and Company A's prescription drug plan, then Company A can issue a single, combined disclosure notice to such individual. However, if a Part D eligible individual participates in Company A's HRA and Company B's prescription drug plan, Company A must issue a disclosure notice to such individual that only takes into account his/her participation in the HRA.

CMS Response:

CMS agreed with the proposed answer.

6. Disclosure Notices in Languages Other than English.

Question #6: CMS has provided model disclosure notices in Spanish. However, the February 15, 2007 disclosure notice guidance does not appear to require a plan sponsor to issue disclosure notices in a non-English language. This appears to also be true even if the majority of the Part D eligible individuals that are enrolled in the sponsor's prescription drug plan speak a language other than English. Is a plan sponsor required to issue disclosure notices in a language other than English?

Proposed Answer #6: Based on the language of the February 15, 2007 guidance, a plan sponsor is not required to issue a disclosure notice in any particular language.

CMS Response:

There is no Part D requirement to provide a notice in languages other than English. However, other requirements, such as ERISA, may require the issuance of non-English Part D notices.

7. RDS Issues.

Question #7: A plan sponsor has applied and has been receiving payments under the Retiree Drug Subsidy program. The plan's PBM has been submitting interim cost reports, and the plan has received RDS payments based on these interim cost reports. The PBM also submits information to CMS for reconciliation of claims, rebate and other information. After reconciliation CMS discovers during an audit that claims for Part B drugs have been mistakenly submitted and paid for by CMS. Is this a violation under the

RDS program? Who is liable? Would it make a difference whether the mistake was found and corrected before final reconciliation occurred? Would there still be a violation if the plan had taken advantage of the simplified methodology for extracting certain Part B costs from RDS payment requests (and the claims in question were within the three categories of drugs where this simplified methodology applies)?

Proposed Answer #7: The federal False Claims Act would apply to those who intentionally submitted false claims to CMS. Under RDS the plan sponsor would be liable for any violations that result from intentional conduct found after final reconciliation. However, innocent mistakes or negligent misrepresentations are not violations. The use of the simplified methodology regarding Part B versus Part D claims acts as a safe harbor under the RDS program, and will not result in a violation if these Part B costs are included in claims submissions.

CMS Response:

CMS agreed with the proposed answer. The False Claims Act only covers false claims, so inadvertent errors are not covered. Further, whether an error was preceding or subsequent to reconciliation does not affect the analysis. If it is a false claim, then it is a violation whether before or after reconciliation.

For inadvertent mistakes and errors not covered by the False Claims Act, the plan sponsor may be liable for the amount of an overpayment if it is not discovered until after reconciliation.

The simplified method of reporting does act as a safe harbor, but CMS expects plan sponsors to act consistently with the reporting method that is used.

The statutory structure holds the plan sponsor liable for violations. However, a plan sponsor can protect itself by having appropriate agreements with vendors and having clear delineation as to who is responsible for performing the RDS calculations and the process for auditing and monitoring.

8. Audits.

Question #8: What are CMS's plans for auditing plans under the RDS? Will audits take place before reconciliation is completed? Will plans be audited every three years just as Part D prescription drug plans? If problems are discovered, what penalties can be imposed. Please also explain the role of the HHS Office of the Inspector General concerning RDS audits.

CMS Response:

The audit process is still evolving and therefore CMS cannot respond at this time. Further, the Inspector General will have a separate audit process from CMS.

Medicaid

9. Encouraging Enrollment in Medicaid versus Employer's Group Health Plan.

Question #9: Recently, some employers have been encouraging their employees to sign up for Medicaid instead of the employer's group health plan, if the employer believes that the employee would be Medicaid eligible. This encouragement can consist of (1) reminding employees that they would not have to pay the employee portion of the employer's group health plan premium if they signed up for Medicaid rather than the employer's plan and (2) assisting employees with signing up for Medicaid by providing the forms and completing the forms for the employees. Based on this encouragement, some employees then do not enroll in the employer's group health plan, even though they are eligible to enroll.

9(a): Does this practice violate the Medicaid rules?

9(b): Does your answer change if the employer provided a direct financial incentive?

CMS Response:

Most states already have regulations that address these practices. The Deficit Reduction Act also has certain requirements on this issue that makes employers responsible for collecting where Medicaid should not have paid primary.

10. Encouraging Use of Medicaid While Enrolled in Employer's Group Health Plan.

Question #10: Along the lines of the previous question, some employers also encourage their employees who are enrolled in the employer's group health plan to use Medicaid rather than the employer's group health plan when filing claims. This practice includes instructing employee-participants (1) to file their claims with Medicaid and not with the employer's group health plan and (2) to inform providers that the employee-participant does not have any employer coverage.

10(a): Does this practice violate the Medicaid rules?

10(b): Does your answer change if the employer provided a direct financial incentive?

CMS Response:

Most states already have regulations that address these practices. The Deficit Reduction Act also has certain requirements on this issue that makes employers responsible for collecting where Medicaid should not have paid primary.

Medicare Secondary Payor

11. Disability.

Question #11: Company ABC has more than 100 employees and has an employee who is under 65 who is receiving Medicare coverage due to disability. The employee does not have End Stage Renal Disease, but another disabling condition. The employee has been receiving long term disability benefits from the Company for more than a year and is on leave without pay. Who pays primary for this individual, Medicare or the Company ABC plan? Does the answer change if the individual is over 65, is on Medicare due to age (not disability) and is receiving long term disability coverage from the Company?

Proposed Answer #11: Medicare is primary in this case. Under regulations at 42 C.F.R. 411.104 an individual will not be considered to have "current enrollment status" if the individual has been receiving disability benefits for an employer for more than six months. However, the Company ABC plan would be primary for an individual with Medicare coverage due to age.

CMS Response:

CMS declined to answer this question because the MSP group had not been able to properly review the question.