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 on May 1, 2006. 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 Security and Related Issues

1. HIPAA Health Plan Identifier Regulations.

**Question #1:** The HHS Semiannual Regulatory Agenda published October 31, 2005 indicates that the health plan identifier proposed regulations may be issued in June 2006. These regulations have been on the agenda for quite some time. When do you foresee the proposed regulations being issued?

**CMS Response #1:** These regulations have been delayed and there is not a specific date for their publication. Because there does not appear to be a major push from the industry to publish these regulations, other, more important issues are taking precedence, including the national provider identifier regulations, claims attachment regulations, and the national health information network initiative.

**Question #2:** The proposed health plan identifier regulations will require all health plans to obtain a unique identifier. Will the proposed regulations provide that a health savings account (HSA) is a health plan for this purpose?

**Proposed Answer #2:** A health savings account is merely a bank account that is owned by an individual for purposes of paying certain qualified medical expenses. A health savings account is not a health plan for this purpose.

**CMS Response #2:** The definition of a “health plan” will be part of the proposed regulations. One of the proposals that CMS is currently considering is whether to specify the status of HSAs and HRAs under the proposed regulations or to provide general guidance regarding how to determine whether a particular plan is a “health plan” subject to the regulations. A specific inquiry to CMS may prompt CMS to issue a FAQ or other guidance related to HSAs and/or HRAs.

CMS is also considering other issues regarding HSAs, such as how providers, health plans and HSAs should work together electronically about taking the money out of the HSA, and whether a provider should be required to give an HSA participant, who has not satisfied the deductible under the high deductible health plan, a network discount that would apply under the high deductible health plan once the deductible is satisfied.

2. HIPAA Security Audit Initiatives.

**Question:** Does CMS have any current or proposed initiatives to enforce or audit group health plans concerning the HIPAA Security Rules? If so, can you describe what those initiatives may be?

**CMS Response:** CMS has the right to audit health plans concerning the HIPAA Security Rules. However, currently CMS is only responding to complaints that are made. In the future, CMS may develop an audit program for the HIPAA Security Rules and if it did
develop such an audit program it would be in combination with any audit program that would be established by OCR for the HIPAA Privacy Rules.

CMS and OCR currently work together regarding any complaints that are received. If a complaint that is received by OCR appears to be a HIPAA security issue, OCR will forward the complaint to CMS. Similarly, if a complaint that is received by MS appears to be a HIPAA privacy issue, CMS will forward the complaint to OCR.

Currently, CMS has received approximately 100 complaints regarding the HIPAA Security Rules and approximately 400 complaints regarding the HIPAA Electronic Transaction Rules. Due to the low number of complaints received, CMS has not formulated any consistent themes as to the types of complaints. However, regarding the HIPAA Electronic Transaction Rules, there are a number of complaints from providers, whereby a provider sent a HIPAA compliant electronic transaction and a health plan did not accept the codes and the provider did not receive payment for those services. There appears to be a misunderstanding on the part of providers that a provider can receive payment for any CBT code on the transmission. However, typically the reason that the provider did not receive payment is that the health plan does not cover that procedure.

In addition, if CMS were to receive a complaint that appeared to violate the criminal provisions of HIPAA, CMS will refer the complaint to the Department of Justice for appropriate action. Currently, CMS has referred approximately 24 complaints to the Department of Justice.

3. **HIPAA Security Enforcement.**

**Question:** How might CMS respond to the following situations involving the final HIPAA enforcement rule?

(a) Self-insured group health plan with 10,000 employees and over $5,000,000 in annual claims complies in all material respects with the HIPAA privacy rule but has taken no steps toward compliance with the HIPAA security rule. In response to a complaint by a plan participant, CMS contacts the employer and discovers the failure. Would CMS engage in a dialog with the plan sponsor about what compliance steps are required and solicit a promise of compliance with a timetable for completion, or immediately initiate formal enforcement action under the HIPAA enforcement rule?

(b) Same facts as in part (a) except that plan sponsor has 400 employees and less than $5,000,000 in annual claims?

(c) Same facts as in part (a) except that plan sponsor has appointed a security official, timely amended its plan to conform to the requirements of the security rule, entered into appropriate business associate agreements, but has not adopted any policies and procedures related to the HIPAA Security Rule and has not trained the plan’s workforce regarding any policies and procedures.
**Proposed Answer:** In each case, CMS would first seek to encourage compliance according to an agreed upon timetable before initiating a formal action under the HIPAA enforcement rule.

**CMS Response:** If any of the above situations occurred and CMS received a complaint, CMS would gather all the facts and make a determination based on its inquiry. The inquiry would begin by CMS contacting the plan administrator or whoever has legal authority over the plan. The plan would receive a letter indicating that a complaint has been filed and request comments from the plan regarding the complaint. CMS would then investigate the plan based on the complaint and the plan’s response to its inquiry letter. If in fact no steps had been taken to comply with the HIPAA Security Rules, then CMS would discuss with the plan a corrective action plan and when the plan will comply.

If a complaint was filed and the health plan did perform a risk analysis, but did not have a written report of the risk analysis, the health plan would need to contact the entity that performed the analysis and either obtain a written report or recreate the risk analysis and write a report.

**Follow-Up Question #1:** CMS was asked to address certain specific HIPAA Security Rule requirements, such as (a) the requirement to have a contingency back up plan, if the plan has no data on site and the third party administrator maintains all the data and (b) issues relating to the periodic review of security compliance initiatives.

**CMS Response:** CMS indicated that in this situation the plan can rely on the third party administrator's back up plan and suggested that the plan include such a statement in its business associate agreement with the third party administrator and in the plan’s written risk assessment.

In addition, a health plan must periodically review its HIPAA security compliance, including for changes that occur in the environment in which the health plan operates. If a company follows the requirements of Sarbanes Oxley or Gramm Leach Bliley and the requirements of those laws also satisfy the requirements of the HIPAA Security Rules, a security risk assessment under those laws would also satisfy the requirements of the HIPAA Security Rules to the extent the rules are similar and are applicable. There is no requirement that a health plan do a separate risk analysis solely for the HIPAA Security Rules.

**Medicare Secondary Payer**

4. **Medicare Secondary Payer and Health Savings Accounts.**

**Background:** 42 CFR Section 411.102(b) provides that a group health plan of an employer with at least 20 employees may not take into account the age-based Medicare
entitlement of an individual or spouse age 65 or older who is covered or who seeks to be
covered under the employer’s health plan. In addition, 42 CFR Section 411.103 provides
that an employer is prohibited from offering Medicare beneficiaries financial or other
benefits as incentives not to enroll in, or to terminate enrollment, in a group health plan
that is, or would be, primary to Medicare.

Employer sponsors a health plan that is a high deductible health plan within the meaning
of IRC Section 223. Employer also makes contributions to the health savings account
(HSA) of an employee who is enrolled in the high deductible health plan. However, if an
employee is enrolled in Medicare, the employee and his or her employer are not eligible
to make contributions to an HSA. See, IRC section 223(b)(7).

**Question #1:** If an employee enrolls in an employer’s high deductible health plan and
the employee is also enrolled in Medicare, the employer is prohibited from making a
contribution to an HSA of that individual. Even though the employer is prohibited from
making an HSA contribution for Medicare enrollees, do the Medicare Secondary Payor
rules require the employer to provide an equal payment to the Medicare enrollees outside
of an HSA?

**Proposed Answer #1:** In this example, the Medicare enrollee is still enrolled in the high
deductible health plan that is primary to Medicare. Even though the employer cannot
make an HSA contribution for a Medicare enrollee, the Medicare Secondary Payor rules
do not require an equal payment outside of the HSA to a Medicare enrollee.

**CMS Response:** CMS provided that it will send a written response to the JCEB
regarding this question.

**Question #2:** Using the same facts as provided above, because a Medicare enrollee
would not be eligible for an HSA contribution, the employer allows Medicare enrollees to
waive participation in the high deductible health plan. At this point, because the
Medicare enrollee is no longer participating in a group health plan, Medicare becomes the
primary payor. If a Medicare enrollee waives participation in the high deductible health
plan, the employer provides the Medicare enrollee with a make-up payment (that is
treated as taxable cash compensation) so that the Medicare enrollee may purchase
individual insurance. If an employer provides such a payment, will the payment violate
the provisions of 42 CFR Sections 411.103 or 411.102?

**Proposed Answer #2:** Because a Medicare enrollee is not eligible to receive an HSA
contribution, the Medicare enrollee may not wish to enroll in the high deductible health
plan, which is structured to operate in conjunction with the HSA. Under 42 CFR
411.172(c), a Medicare enrollee may refuse to accept the health plan offered by the
employer. If the employee refuses to enroll in the health plan, then Medicare is the
primary payor. Therefore, the employer is not paying the Medicare enrollee to not enroll
in the high deductible health plan. Rather, the employer is providing a make-up payment
that is roughly equal to the value of the high deductible health plan coverage, if the
Medicare enrollee chooses not to enroll. Therefore, the provisions of 42 CFR Sections 411.103 and 411.102 are not violated.

**CMS Response:** CMS provided that it will send a written response to the JCEB regarding this question.

5. **Medicare Secondary Payor Exception for Multi-Employer Plans.**

**Question:** If an employer participates in a multi-employer health plan and the employer has less than 20 employees, the employer may request an exemption from the working aged rules. See, 42 CFR Section 411.172. If an employer requests such an exemption, then Medicare is the primary payor and the multi-employer health plan (with respect to that employer’s employees) is the secondary payor. Once such an employer requests the exemption and the exemption is approved, does the employer need to update the exemption each time the employer hires or terminates an employee? If so, does the exemption only need to be updated if the employer hires or terminates a Medicare-eligible employee, or if the employer’s employees increase to 20 or more? Further, if the exemption must be updated, how does the employer notify CMS of the updates?

**CMS Response:** CMS provided that it will send a written response to the JCEB regarding this question.

6. **Medicare Secondary Payor and Multi-Employer Plans.**

**Question:** If an employer participates in a multi-employer health plan, the employer usually has little if any access to the data necessary to respond to a Medicare Secondary Payor inquiry. This problem of data access is often exacerbated by HIPAA privacy concerns raised by the multi-employer plan and a general lack of bargaining power over the plan. However, recent interim final rules issued February 24, 2006 and effective April 25, 2006 expand the definition of "primary payers" to include employers who contribute to a group health plan and also permit recovery of payment and double damages from such entities. These modifications are retroactively effective. If an employer contributes to a multi-employer plan, is the employer considered to be a "primary payer" under the interim final rules?

**Proposed Answer:** In the instance where an employer is contributing to a multi-employer plan under a collective bargaining agreement (as defined in ERISA section 3(37)) , and has no other involvement in the plan other than to forward premiums to the plan, the multi-employer plan, and not the contributing employer, is the sole "primary payer" under regulations section 411.21.

**CMS Response:** CMS provided that it will send a written response to the JCEB regarding this question.
Follow-Up Question: For multi-employer plans it may make some sense to have joint and several liability as a primary payor, because these are union groups and the employees typically move around among different employers while covered by same plan. However, for multiple employer plans, the employers are unrelated and the employees typically do not move around between employers and therefore there is more of an argument that a multiple employer plan should not have joint and several liability as a primary payor.

CMS Response: CMS provided that it will send a written response to the JCEB regarding this question.

7. MSP Rules for HRAs.

Question: IRS Notice 2002-45 provides guidance regarding Health Reimbursement Arrangements or “HRAs.” Typically, an HRA is combined with a high deductible health plan that is either insured or self-insured. However, the HRA accounts will be entirely funded by employers, to reimburse employees and their dependents for medical expenses not otherwise covered by the regular group health plan. Because there is no opportunity for the individuals to receive the funds for anything other than qualifying medical expenses under Code Section 213(d), Section 125 is not needed in order to make the HRA reimbursements free from tax. Therefore, they fall outside the exemption articulated in your May 28, 2002 letter regarding Section 125 cafeteria plans. However, administering these generally small accounts will be much more complicated if the accounts must be primary to Medicare for the employees receiving Medicare benefits (or those with family members receiving Medicare benefits). Is it CMS’ position that HRA accounts must be exhausted before Medicare is required to pay any amounts not otherwise covered by the regular group health plan covering the employee or family member?

Proposed Answer #1: No, payments made to employees or their family members pursuant to an HRA that complies with the requirements of IRS Notice 2002-45 will not be required to be primary to Medicare.

Proposed Answer #2: HRA accounts that provide maximum benefits no greater than twice the employee contribution or $500 more than the employee contribution, and which are offered to individuals who are already offered coverage by another regular major medical plan of an employer will be exempt from MSP. (Based upon the exemption from HIPAA for health FSAs. See, Treas. Reg. 54.9831-1(c)(3)(v).)

CMS Response: CMS provided that it will send a written response to the JCEB regarding this question.
8. Medicare Secondary Payor and Part D.

**Question:** Does Medicare Part D do anything to change the general Medicare secondary payor rules? For example, if an employee is age 65 or older and is working for an employer and is covered by the employer’s group health plan that provides prescription drug benefits, the employer group health plan will be the primary payor and Medicare will be the secondary payor. Does this result change if the employee happens to enroll in Part D coverage even though his/her employer’s group health plan is providing him/her with prescription drug coverage that is creditable?

**Proposed Answer:** No. If an employee age 65 or older enrolls in Medicare Part D while remaining enrolled in his/her employer’s group health plan that provides creditable prescription drug coverage, the employer’s group health plan will remain the primary payor for both medical and prescription drug claims.

**CMS Response:** CMS provided that it will send a written response to the JCEB regarding this question.

9. Health Flexible Spending Accounts.

**Question:** In your May 28, 2002 letter you provided that health flexible spending accounts that are provided through a Section 125 cafeteria plan would be exempt from the MSP rules. (A copy of this letter is attached to these Questions.) Health flexible spending accounts are funded by employee pre-tax salary contributions and are treated as self-insured health plans under the Tax Code. On February 24, 2006, CMS issued interim final amendments to the MSP regulations that provided a definition of a “self insured plan.” This definition could be broad enough to include health flexible spending accounts. Were the interim final amendments intended to include health flexible spending accounts provided through a Code section 125 cafeteria plan as being subject to the MSP regulations?

**Proposed Answer:** No. Based on the May 28, 2002 letter, the position of CMS is that health flexible spending accounts that are provided through Code section 125 cafeteria plans as discussed in the May 28, 2002 letter are not subject to the MSP rules.

**CMS Response:** CMS provided that it will send a written response to the JCEB regarding this question.


Medicare Part D


Facts: An employer maintains separate group health plans – one covering only active employees (and their eligible family members), and another covering only retirees (and their eligible family members). The employer will apply for the retiree drug subsidy with respect to its retiree group health plan, and will obtain the required annual actuarial attestation (for purposes of both the retiree drug subsidy application and Part D creditable coverage notice requirement).

Question: Although the employer is electing the retiree drug subsidy on behalf of its separate group health plan covering retirees (and their eligible family members), must that employer obtain an annual actuarial attestation on behalf of its separate active group health plan in connection with issuing the Part D creditable coverage notice, or can that employer rely on the simplified determination of Part D creditable coverage status annually?

Proposed Answer: A separate (or stand-alone) active group health plan need not obtain an annual actuarial attestation when determining Part D creditable coverage status. Instead, the plan sponsor can rely on the simplified determination of Part D creditable coverage status annually, as described in CMS guidance.

Explanation: The final rules under Medicare Part D do not appear to require an actuarial attestation when determining creditable coverage status. However, guidance posted by CMS [http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCGuidance.pdf](http://www.cms.hhs.gov/CreditableCoverage/Downloads/CCGuidance.pdf) states that "[t]he determination of creditable coverage status does not require attestation by a qualified actuary unless the entity is an employer or union electing the retiree drug subsidy. See the regulation at 42 CFR §423.884(d). [Requirements for qualified retiree prescription drug plans. Actuarial attestation – general.]" A literal reading of such CMS guidance suggests that any employer who elects to apply for the retiree drug subsidy must obtain an actuarial attestation when determining creditable coverage status under any of its group health plans covering Medicare eligible individuals, including group health plans covering its active employees (and their eligible family members) that are not eligible to apply for the retiree drug subsidy. CMS guidance should clarify that the actuarial attestation when determining Part D creditable coverage status does not apply with respect to any “benefit option” for which an employer (or union) is not electing the retiree drug subsidy. This would be particularly helpful since many employers maintain separate group health plans for their active employee and retiree population.

With regard to the determination of Part D creditable coverage status, the aforementioned CMS guidance states: “This determination is identical to the first prong of the actuarial equivalence test (gross test) that is applied in the regulation at 42 CFR §423.884(d) when an employer or union applies for the retiree drug subsidy under that section. … For plans that have multiple benefit options, the regulation requires that entities apply the actuarial [gross] value test separately for each benefit option. A benefit option is defined in the
regulation at 42 CFR §§423.882 as a particular benefit design, category of benefits, or cost-sharing arrangement offered with a group health plan.”

Based on the cross-reference to 42 CFR §423.884(d), one could reasonably infer that an actuarial attestation should be required for purposes of determining Part D creditable coverage status only with respect to a “benefit option” for which a sponsor requests the retiree drug subsidy. In other words, since CMS guidance states that the "gross value" test (which must be applied separately for each "benefit option" for which a sponsor requests a retiree drug subsidy) must be applied for purposes of determining Part D creditable coverage status, an actuarial attestation for such purposes should only be required for each “benefit option” that is required to obtain a corresponding actuarial attestation for purposes of applying for the retiree drug subsidy.

Because an employer is not permitted to request a retiree drug subsidy on behalf of its active Medicare-eligible individuals, an actuarial attestation for an employer’s benefit options covering only active employees (and their eligible family members), which is offered under a separate active group health plan, should not be required for determining Part D creditable coverage status, irrespective of whether the employer chooses to elect the retiree drug subsidy with respect to any benefit option covering qualifying covered retirees under a separate retiree group health plan. Instead, for purposes of determining Part D creditable coverage status under a separate active group health plan, the employer should be allowed to rely on the simplified method. Otherwise, the employer would need to undertake unnecessary costs and administrative burdens in satisfying the Part D creditable coverage status requirement on behalf of an active group health plan that is not eligible to receive the retiree drug subsidy (i.e., the same concern expressed in the preamble to the final rules under Medicare Part D, which focused on employers who did not elect the retiree drug subsidy altogether). This concern becomes magnified where an employer maintains various separate active group health plans covering its nation-wide workforce.

**CMS Response:** CMS indicated that the question was thoughtful and that they will be publishing additional guidance in the Federal Register. When this guidance is published, this question should be submitted during the comment period so that it can be officially considered.

11. **Draft of May 15, 2006 Guidance on Notices of Creditable Coverage.**

**Question #1:** In May 2005 CMS issued guidance regarding Notices of Creditable Coverage (“NOCC”). This guidance, in part, provided that the NOCC must be provided prior to the Medicare Part D Annual Coordinated Election Period each year and prior to an individual’s Initial Enrollment Period for Part D. The guidance also provided that “prior to” means that the beneficiary must be provided the NOCC within the past 12 months, and that CMS will consider both of these rules to be satisfied if the NOCC is provided to all plan participants. Based on these rules, many plan sponsors furnished the NOCC to all plan participants in November 2005, and were not planning on issuing the NOCC again to all plan participants until November 2006. In reviewing the draft
guidance to be effective May 15, 2006, the updated guidance provides that the new NOCCs must be used after May 15, 2006. Therefore, does the updated guidance require that plan sponsors distribute new NOCCs for those participants that have an initial enrollment period after May 15, 2006 and before November 2006 when the plan sponsor (in this example) would furnish another annual NOCC based on the updated guidance?

**Proposed Answer #1:** No. Plan sponsors may rely on the prior guidance in providing NOCCs on an annual basis and would not be required to re-issue a NOCC that was issued to all plan participants in November 2005 solely due to an individual’s initial enrollment period occurring after May 15, 2006 and before the prior NOCCs’ 12-month period would expire. However, the updated NOCC’s must be used after May 15, 2006 if an individual newly joins the plan, the plan’s creditable coverage status changes, or upon request by a beneficiary.

**CMS Response:** CMS agreed with the proposed answer and also indicated that under the guidance no entity is required to use the model notices. However, all notices must inform individuals of the items that are required to be in the notice.

**Question #2:** The updated draft guidance effective May 15, 2006 provides on page 11 that a personalized NOCC “can be provided” to a beneficiary by the plan upon request or in lieu of a Model NOCC. The guidance also provides that a personalized NOCC “should be provided” upon request by a beneficiary. The personalized NOCC requires that a plan include the period of time that the Part D eligible individual was covered by the plan. This would require plans to retain the date that the person became covered under the plan as long as the Part D eligible individual was covered under the plan. This period may span decades. Currently, many plans do not retain the date that a person became covered under a plan. Further, if they do retain this date, due to data conversions and other database issues, such date may not be retained after a certain number of years. Therefore, based on the foregoing, did CMS intend to require plans to issue personalized NOCCs upon request by an individual, or can a plan alternatively issue the model NOCC upon request?

**Proposed Answer #2:** Page 6 of the updated guidance effective as of May 15, 2006 clarifies that plans are not required to use any of the model NOCCs. As a consequence, a plan can fully comply with a beneficiary’s request or any other requirement to issue a NOCC by issuing an alternative NOCC or the standard model NOCC to a beneficiary. A plan never has to use the personalized NOCC, or any of its suggested data elements, in any creditable coverage communications with a beneficiary, CMS, or a Part D plan.

**CMS Response:** The personalized model notice is not required, but it is encouraged, and the suggested data elements of a personalized notice are also not required.

**Question #3:** The updated draft guidance effective May 15, 2006 provides on page 2 that a NOCC must be provided to all Part D eligible individuals who are covered under, or who apply for, the entity's prescription drug coverage. This applies to all active employees, disabled, on COBRA, and retired, as well as Medicare beneficiaries who are
covered as spouses or dependents under active employee coverage and retiree coverage. Because many employers have only partial data regarding the age or Medicare status of spouses and dependents, they have elected to distribute the NOCC to all employees, even those who are decades away from becoming a Part D eligible individual. This has increased the administrative burden and costs associated with distributing the NOCCs. Is it permissible for employers to limit the distribution of the NOCC across their workforce?

**Proposed Answer #3:** While the draft guidance and the related regulations do not recognize an exception to the obligation to distribute the NOCC, employers may, but are not required to, adopt reasonable standards for the distribution of the NOCC. For example, employers may choose to only distribute the NOCC to employees age 55 or older, as long as they remind all employees through annual enrollment materials or a Summary Plan Description that the NOCC is available upon request and how to obtain it.

**CMS Response:** CMS indicated that all Part D eligible individuals must receive the notice. In determining who is Part D eligible, a plan should use a reasonable method to make the determination. A plan could work through its third party administrator in targeting the specific people. CMS indicated that depending upon the specific facts that sending the notice to all employees age 55 or older and reminding all employees (regardless of age) through annual enrollment materials or an SPD that a notice is available upon request may be a defensible means of targeting Part D eligible individuals.

12. **Employer Bankruptcy / Closure of Business.**

**Question:** Some employers have not issued a NOCC or filed with CMS through its website regarding its NOCC, because the employers have believed that they did not cover any Medicare Part D eligible individuals. If a Medicare Part D eligible individual was covered under an employer group health plan, and the employer did not send a NOCC or file with CMS through its website regarding its NOCC, how does a Medicare Part D eligible individual later prove to CMS that he/she had creditable coverage if the employer has gone out of business and there is no successor employer or successor health plan from which to obtain any enrollment records?

**CMS Response:** CMS indicated that this issue is not solely within the employer policy group which attended the meeting. The late enrollment penalty is also within another CMS group that did not attend the JCEB meeting. Therefore, CMS could not fully address this question. However, in general, Section 423.56(g) provides appeal rights to beneficiaries that are charged the late enrollment penalty. In order to waive the penalty, the beneficiary must, among other things, show an attempt to request the notice in writing. In addition, there are other ways that an individual can prove to CMS that he or she had creditable coverage for those who cannot obtain a creditable coverage notice after requesting one.