April 1, 2014

Submitted electronically via http://www.regulations.gov

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0037-P
P.O. Box 8013
Baltimore, MD 21244-8013

Subject: Administrative Simplification: Certification of Compliance for Health Plans (CMS-0037-P) – ABC Comments

Sir or Madam:

I write on behalf of the American Benefits Council ("Council") to offer comments in response to the Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) Proposed Rule on Administrative Simplification: Certification of Compliance for Health Plans (CMS-0037-P) ("Proposed Rule"), published in the Federal Register on January 2, 2014 (79 Fed. Reg. 298).

The Council is a public policy organization representing principally Fortune 500 companies and other organizations that assist employers of all sizes in providing benefits to employees. Collectively, the Council's members either sponsor directly or provide services to health and retirement plans that cover more than 100 million Americans.

We appreciate the opportunity to provide comments in connection with the Proposed Rule pursuant to Section 1104 of the Affordable Care Act ("ACA"), which requires health plans to certify compliance with certain applicable standards and associated operating rules adopted by the Secretary under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

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CERTIFICATION BY SELF-INSURED GROUP HEALTH PLANS

The Proposed Rule establishes certification requirements that are intended to align with the requirements and timelines under the Unique Health Plan Identifier Final Rule (HPID Final Rule). Specifically, the proposed rule would require certification at the CHP level and the Secretary proposes that *all* "controlling health plans" (CHPs) meet the certification submission requirements.

As a threshold matter, we request that final regulations clarify that where a group health plan fulfills its obligation to provide benefits through the purchase of insurance, the insurer or HMO is the controlling health plan and that the group health plan has no obligation under the Proposed Rule. The Council believes that this would almost always be the case and that clarification will serve to avoid confusion regarding compliance obligations.

The preamble to the HPID Final Rule clarified that self-insured employer group health plans meet the HIPAA definition of "health plan" at 45 CFR 160.103 and are thus required under the HPID Final Rule to obtain an HPID, if they meet the definition of a CHP. *See* 75 Fed. Reg. 54664, 54670 (September 5, 2012). A "CHP" is a health plan that controls its own business activities, actions, or policies, or is controlled by an entity that is not a health plan (as well as maintaining control over any of its "subhealth plans"). 45 C.F.R. 162.103. As the HPID Final Rule acknowledged, however, "very few" self-insured group health plans "conduct standard transactions themselves; rather, they typically contract with TPAs or insurance issuers to administer the plans." 75 Fed. Reg. at 54696. The Secretary concluded by stating that "only health plans that use the HPIDs in standard transactions will have direct costs and benefits" associated with the requirement to obtain an HPID. *Id.*

Under the Proposed Rule, however, *all* health plans that meet the definition of a CHP are required to meet the certification requirements. This appears to be the case regardless whether they actually conduct any standard transactions. The Proposed Rule does not explicitly address the responsibilities of the self-insured plan and the plan administrator with respect to meeting certification requirements in those cases. In the vast majority of these situations, the self-insured group health plan is not self-administered and does not engage in standard transactions, but utilizes third parties to administer the plan, including carrying out any covered transactions.

Under proposed sections 162.926(a)(2) and (b)(2), a CHP has the option of selecting the HIPAA Credential as one of two alternatives for meeting the first certification of compliance submission requirements. Even assuming that this alternative was intended to provide a simplified option for certifying compliance, we believe the Proposed Rule underestimates the complexity of the process for self-insured group health plans to obtain the HIPAA Credential.

The HIPAA Credential is administered by CAQH CORE and demonstrates that a CHP has attested to compliance with HIPAA standards and operating rules for the eligibility for a health plan, health care claim status, and electronic funds transfers (EFT) and remittance advice transactions. The HIPAA Credential has not been finalized and is under development by CAQH CORE. Nonetheless, the Proposed Rule makes clear that obtaining a HIPAA Credential will require the CHP to have a certain level of testing with its "trading partners."

In order to obtain the HIPAA Credential, the CHP will be required to submit an attestation form in which the CHP confirms that it has successfully tested the operating rules for the eligibility for a health plan, health care claim status, and health care electronic funds transfers (EFT) and remittance advice transactions with trading partners that, collectively, account for at least 30 percent of the total number of transactions conducted with providers. *See* 79 Fed. Reg. at 305. The Proposed Rule states that for each of the three transactions, the CHP must confirm that it has successfully tested with at least three trading partners, but if the number of transactions conducted with three trading partners does not account for at least 30 percent of the total number of transactions conducted with providers, the CHP could confirm that it has successfully tested with up to 25 trading partners. *Id.* The CHP would have to list those trading partners, and would have to provide contact information, including, but not limited to, name, phone number, and email address, for each of the listed trading partners. *Id.*

Clearly, plans that are administered by a third party administrator (TPA) or another health plan under an administrative services only (ASO) agreement are not engaged in standard transactions with trading partners. In many, if not most cases, such self-insured group health plans do not have direct contractual arrangements with such trading partners, and do not maintain the kind of detailed information on such partners that must be provided. Moreover, a plan might have multiple arrangements, and each separate arrangement would need to be analyzed in order to make the certification. For instance, a single group health plan might have one vendor to process eligibility and enrollment transactions, another vendor that engages in claims processing and payment, and there may be distinct vendors for different components of the health plan (e.g., different vendors or arrangements for mental health or prescription drug coverage).

Thus, a self-insured group health plan can impose obligations necessary to fulfill the certification requirement only through its arrangement with those third parties that actually carry out standard transactions in the administration of the plan, and the multiplicity of such arrangements could make the effort both time-consuming and burdensome.

Effectively, many self-insured group health plans have no choice but to rely on their third party plan administrator(s) to complete and submit certification requirements on

its behalf, a significant and unnecessary administrative burden for self-insured group health plans that are utilizing vendors and/or business associates that have obtained their own certifications.

The Council requests that final regulations clarify that CHPs that are not engaged in standard transactions are exempt from the certification requirements under the Proposed Rule.

If the Secretary intends for such CHPs to certify compliance, we recommend that the final rule provide a third option for self-insured plans that do not themselves engage in any standard transactions. Specifically, the Secretary should provide an option for the plan to certify that it is under arrangement with an entity to carry out administration of the plan and that such other entity or entities have obtained CORE Phase III Seal or HIPAA Credential and certified compliance, and such other information reasonably required to allow the Secretary to confirm compliance. In such cases, we do not believe that it is reasonable or practical to require certification and testing that is specific to each self-insured plan that is administered by a third party that administers dozens if not hundreds of similar plans. Testing on behalf of each plan (e.g., using that plan's transaction history to identify trading partners that account for 30% of transactions for that specific plan) would almost certainly result in overlapping, duplicative and ultimately unnecessary testing. Such an outcome is administratively burdensome and costly and counter to the goals of HIPAA Administrative Simplification to achieve efficiencies in the health care system.

If the final rule requires certification by self-insured group health plans, we recommend that such requirements be significantly simplified where the plan conducts no transactions. At a minimum, the final rule should allow a plan administrator to act on behalf of self-insured group health plans in providing documentation indicating a CORE Phase III Seal or HIPAA Credential. Further, it should permit a self-insured group health plan that is a CHP to reasonably rely upon written representations from business associates that they have complied with the certification requirement.

APPLICATION TO HEALTH SPENDING ARRANGEMENTS

The Council requests that the Secretary provide specific guidance on whether or how the proposed regulations are intended to apply to those employee benefit plan arrangements, such as flexible spending arrangements (FSAs) and health care reimbursement accounts (HRAs), and health savings accounts (HSAs) that typically provide for reimbursement by the plan to the individual employee or plan participant. These arrangements typically have no standard transactions between covered entities, by the plan itself or through vendors. As with self-insured group health plans that do not directly conduct transactions, the Council requests that these types of plans be exempted from the certification requirements under the proposed regulations even if

they otherwise meet the definition of a CHP. If the Secretary believes these plans are not exempt, the Council requests that the Secretary provide specific guidance for how plans are expected to provide a certification, and a simplified method for obtaining such certification.

SUBMISSION OF INFORMATION ON COVERED LIVES

Under the Proposed Rules, CHPs are required to submit information on the number of covered lives as part of the certification requirements under § 160.926(a)(1) and (b)(1). According to the regulatory preamble, the submission of information on covered lives is necessary to calculate penalty fees. *As acknowledged in the preamble, the statute does not require the submission of such information.*

While Section 1173(j)(1) of the Act specifies that the penalty fee amount assessed when a health plan does not meet the certification of compliance requirements is based on its number of covered lives, section 1173(j)(1)(F) of the Act requires the Secretary to determine the number of covered lives under a health plan ''based upon the most recent statements and filings that have been submitted by such plan to the Securities and Exchange Commission'' (SEC). The Secretary has determined that the SEC is an unreliable and incomplete source for such information and has thus proposed the submission called for in the Proposed Rule. *See* 79 Fed. Reg. at 312.

The Council strongly opposes reporting of covered lives as proposed and believes that any requirement to collect and report such information is unreasonable and unnecessary in advance of any allegation, let alone a final finding, that a violation has occurred and a penalty should be imposed. Such a rule imposes a substantial regulatory burden based solely on the possibility that a penalty might be imposed.

We further recommend that any penalties calculated on the basis of number of covered lives be based on a plan's enrollment when a violation has been determined. We believe that is the intent of Congress under the statute. Whether or not SEC filings provide sufficient information to ascertain the number of covered lives, the statutory enactment clearly requires that such information will be current as it is based on the entity's *most recent* filings. The number of participants in a plan fluctuates, sometimes significantly in relation to hiring, termination and changes in eligibility. Information on the number of covered lives that was submitted at a date prior to any finding of violation would be an unsound basis for the determination of penalty amounts.

Finally, the Council is concerned that the Secretary underestimates the complexity of ascertaining the "number of covered lives" as of any given date. For instance, one entity might have multiple CHPs with overlapping membership and enrollment. Any requirements in final regulations to report number of covered lives or for the use of number of covered lives for purposes of penalty assessment should include an anti-

double counting rule. Regulations implementing ACA provisions that have assessed fees on a per covered life basis, including for example, to fund the Patient-Centered Outcomes Research Institute (PCORI) included such a rule.

PRIVACY AND SECURITY

The Proposed Regulations also include requirements for certifying compliance with privacy and security provisions of HIPAA. We believe these requirements are overly broad and not consistent with the statutory provisions. The current requirements for voluntary CAQH CORE Certification include attestation of compliance with the HIPAA privacy and security provisions through the CAQH CORE HIPAA Attestation form. The Secretary notes in the preamble that it anticipates the HIPAA Credential would require the same attestation, which it considers to be an essential document of compliance for purposes of the first certification of compliance. *See* 79 Fed. Reg. at 308.

Section 1104(h)(1)(A) of the ACA specifically requires a health plan to file a statement "certifying that the data and information systems for such plan are in compliance with any applicable standards and associated operating rules." Congress has already enacted laws, and the Secretary has already promulgated rules, covering compliance with HIPAA privacy and security rules and enforcement for violations of those rules.

Certifying compliance with the privacy and security rules as part of certification of compliance with transaction standards and operating rules would be redundant and burdensome. In addition, if such failure to comply with this aspect of the Proposed Rule were to result in a privacy or security rule violation, the Secretary would essentially be creating an alternative enforcement mechanism for HIPAA privacy and security standards that appears to undermine and conflict with the official enforcement role of HHS Office for Civil Rights' (OCR). This "alternative enforcement" was clearly not contemplated by Congress when it enacted the certification requirement for standard transactions.

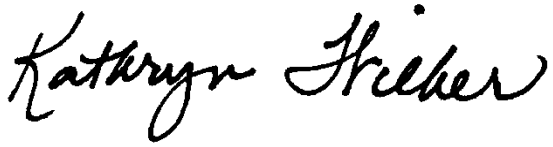
There is currently a statutory and regulatory penalty structure for violations of privacy and security provisions under HIPAA. *See* 45 C.F.R. Part 160, Subparts C (compliance and investigations), D (imposition of civil monetary penalties), and E (procedures for hearings). We strongly believe that OCR should remain the primary agency for interpreting and enforcing privacy and security rules and recommend the final rule not include the requirement for CHPs to attest to compliance with privacy and security provisions in order to meet any obligations under the first certification of compliance.

OPPORTUNITY FOR CORRECTIVE ACTION

The Council believes that because the Proposed Rule would impose significant penalties on CHPs that fail to comply with the certification requirements, it is important for the penalty provisions to allow time and opportunity for correction by the CHP prior to finalizing the certification. A corrective action plan should permit the entities to address missing documentation or minor operating rule and/or standards compliance errors where there is clearly no intent to defraud or not comply. This is particularly important given the potential magnitude of the penalties.

We are pleased to have the opportunity to provide comments regarding the Proposed Rule. If you have any questions or would like to discuss these comments further, please contact me at (202) 289-6700.

Sincerely,



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