April 3, 2014

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0037–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: Administrative Simplification: Certification of Compliance for Health Plans (RIN 0938–AQ85)

Ladies and Gentlemen:

The ERISA Industry Committee (“ERIC”) is pleased to respond to the request of the Department of Health and Human Services (“HHS”) for feedback on the proposed regulations on Administrative Simplification: Certification of Compliance for Health Plans (the “proposed regulations”). The proposed regulations would require employer group health plans to certify compliance with standards and operating rules adopted under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) for electronic transactions relating to eligibility for a health plan, health care claim status, and health care electronic funds transfers (“EFT”) and remittance advice (the “Covered Transactions”).

ERIC’S INTEREST IN THE CERTIFICATION REQUIREMENT

ERIC is a nonprofit association committed to the advancement of the employee retirement, health, and other welfare benefits of America’s largest employers. ERIC’s members sponsor some of the largest private group health plans in the country. ERIC’s members are committed to, and known for, providing high-quality, affordable health care. Our members expend considerable resources to maintain plans that cover many disparate populations across a wide range of geographic areas and that operate in all states and territories. These plans provide health care to millions of workers and their families. Although ERIC’s members comply with HIPAA’s requirements, they are concerned that any mandates that increase the cost and complexity of health plan administration will divert resources that could otherwise be used to provide health benefits to workers and their families.

SUMMARY OF MAJOR COMMENTS

As discussed in detail below, ERIC’s recommendations include:

- Plans that do not engage in Covered Transactions (“Non-Transaction Plans”) should not be required obtain a Council for Affordable Quality Healthcare (“CAQH”) Committee on Operating Rules for Information Exchange (“CORE”) Certification Seal for Phase III CAQH CORE EFT & ERA Operating Rules or HIPAA Credential (collectively referred to as a “CORE Certificate”);

- In any event, HHS should limit the application of the proposed regulations to major medical coverage, in accordance with the approach provided in the regulations outlining the transitional risk reinsurance fee;

- Plans should be subject to the certification requirement only to the extent that they provide medical care; and

- The following changes should also be made:
  - the fee to obtain a seal or certificate for HIPAA compliance should reflect the fact that self-insured plans do not generate net revenue;
  - HHS should clarify that the number of individuals used to calculate the penalty should be based only on the number of individuals covered by or enrolled in insurance policies that are major medical policies; and
  - the regulations should be re-proposed, and the deadline for compliance should be extended.

OVERVIEW

In addition to privacy and security requirements, HIPAA also includes electronic transaction provisions, which are designed to increase efficiency and reduce the cost of health care.

The proposed regulations would require nearly all health plans to provide information and documentation that demonstrates compliance with the HIPAA standards and operating rules for the Covered Transactions. In order to demonstrate that they satisfy these requirements, plans would be required to: (1) obtain a CORE Certificate; (2) report to HHS that they have obtained the CORE Certificate; and (3) notify HHS regarding the number of covered lives for the plan. The CORE Certificate is designed to demonstrate that a health plan has attested to or demonstrated compliance with the HIPAA standards and operating rules for the Covered Transactions.
COMMENTS

I. Plans that do not directly handle Covered Transactions should not be required to obtain a CORE Certificate.

HIPAA’s electronic transaction provisions are designed to increase efficiency and reduce costs. HHS explains in Frequently Asked Questions that “National standards for electronic health care transactions will...result in savings from the reduction in administrative burdens on health care providers and health plans.”

Health plans that do not handle Covered Transactions should not be subject to the certification requirement as it does not advance HIPAA’s objectives and would be unduly burdensome. Executive Order 12866 “Regulatory Planning and Review” and Executive Order 13563 “Improving Regulations and Regulatory Review” direct agencies to balance the additional costs that regulations impose on companies with a corresponding benefit to the system. They also direct agencies to maximize net benefits, promote flexibility and reduce regulatory burdens on companies.

The proposed regulations would apply the certification requirements to all “controlling health plans” (“CHPs”). The statutory language of HIPAA does not use this term; however, the HHS regulations that require CHPs to obtain health plan identifiers (“HPIDs”) defined it broadly to effectively include all “health plans” (other than those plans that are “controlled” by another health plan). The term “health plan” is also defined broadly and seems to include the vast majority of employer-sponsored health plans that are subject to the Employee Retirement Income Security Act of 1974, as amended (“ERISA”).

HHS states in the preamble to the proposed regulations that health plans must demonstrate compliance with the rules even if they use third parties to conduct the Covered Transactions. The preamble states “if a [business associate] that is not a health plan conducts all or part of a transaction on behalf of the CHP or its [sub-health plans], then the CHP is responsible for ensuring the entity conducts any HIPAA standard transactions in accord with any applicable HIPAA transactions standards and operating rules.”

Despite Congress’s desire to reduce costs, the approach taken in the proposed regulations would impose significant costs on Non-Transaction Plans without generating a corresponding benefit. These plans hire companies to perform services for the plan that range from enrolling employees to adjudicating claims to transferring funds. (For more information about the structure of self-insured plans, see Exhibit A.) As these vendors typically deal with the Covered Transactions on behalf of self-insured plans, they are in the best position to make the kinds of attestations or certifications required by the proposed regulations. Because Non-Transaction Plans do not directly handle Covered Transactions, or even have protected health information, no added protections to individuals or cost

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4 45 C.F.R. § 160.103.
savings would be generated by requiring their compliance with the proposed regulations. Additionally, vendors typically perform these services for many health plans. As a result, it would be more efficient and aligned with Congress’s intent to have the vendors that are performing the transactions certify that their procedures comply with HIPAA.

In fact, these plans would incur additional costs to demonstrate compliance with HIPAA. Although HHS does not anticipate the proposed regulations will generate additional costs, our members indicate that the cost to comply with the proposed regulations are expected to be significant in fees both to CAQH and to their vendors. The preamble to the proposed regulations suggests that the fees charged by CAQH for the CORE Certificate for large plans may cost thousands of dollars. Additionally, ERIC’s members have explained that their vendors have indicated that they may charge fees to perform the testing necessary for the plan to obtain a CORE Certificate. It would be unnecessary and costly for health plans that do not handle Covered Transactions to have to obtain certifications for transactions that are already being handled without provider complaints.

Furthermore, HIPAA’s objectives are already being addressed by many of these plans’ vendors. Most third-party administrators are “health care clearinghouses”: they receive eligibility, coverage, and other information in a nonstandard format or with nonstandard content from the employer that sponsors the group health plan, and they process the information into standard format for transmission to health care providers. Health care clearinghouses are “covered entities” that are directly responsible for complying with HIPAA’s transaction standards. If a self-funded group health plan conducts Covered Transactions exclusively through third-party administrators or other vendors that qualify as health care clearinghouses, there is no need for the group health plan to certify that it independently complies with the transaction standards. Additionally, as noted above, the certifications and corresponding costs would be duplicated by the health plans that hire these vendors to perform the Covered Services for them.

Similarly, insurance companies are also directly responsible for complying with these requirements as covered entities as health insurance issuers. When a group health plan (or portion of a plan) is fully insured, HHS should make clear that it is the insurance issuer that is required to satisfy the certification requirement on behalf of itself and also on behalf of the plan it insures. Otherwise, two entities would be required to meet the same certification requirement, and HHS will receive duplicate certifications.

For any vendors that are not already subject to HIPAA’s electronic transaction requirements, Non-Transaction Plans could include the requirement in their agreements that the vendors comply with these electronic transaction requirements. This approach would be considerably less expensive than requiring Non-Transaction Plans to comply directly.

ERIC urges HHS to modify the rules to provide that self-funded plans should be able to comply with the certification requirement by confirming to HHS that they conduct Covered

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6 The preamble to the proposed regulations states “We do not believe section 1173(h)(3) of the Act places any new requirements or burdens on health plans with regard to their BAs that are not already accounted for in § 162.923(c).” 79 Fed. Reg. at 309.
7 See generally, 79 Fed. Reg. at 310. The preamble identifies fees based on net revenue. As self-insured plans have expenses and no net revenue, it is unclear as to the amount of the fees that will be charged.
8 45 C.F.R. § 160.103.
9 Id.; see also Social Security Act § 1172(a).
Transactions exclusively through one or more entities that either (1) are covered entities themselves, and thus are directly required to comply with the HIPAA transaction standards, or (2) have agreed contractually that they will comply with the transaction standards.

II. Plans that are considered to provide excepted benefits should not be subject to the certification requirement.

Certain benefits, known as “excepted benefits,” are not subject to specific provisions in ERISA and the Public Health Service Act. For example, excepted benefits are not required to comply with certain market reforms contained in the Affordable Care Act (“ACA”). The definition of “excepted benefits” can include programs such as limited-scope dental or vision benefits and certain employee assistance programs.

These programs provide important benefits to workers and their families. However, Congress did not want to unduly burden these programs given the types of benefits they provide. For example, limited scope dental programs that are excepted benefits are not required to provide certain benefits that are normally associated with major medical plans, such as the preventive care benefits required by the ACA.

A similar approach should be taken for purposes of the proposed regulations. Compliance with the certification requirement by these programs would be unlikely to generate any significant benefit that could outweigh the substantial burdens placed on these arrangements. ERIC urges HHS to exclude excepted benefits from the definition of plans subject to the proposed regulations.

III. HHS should limit the application of the certification requirement to major medical coverage, in accordance with the approach provided in the regulations outlining the transitional risk reinsurance fee.

HHS should use the same approach for applying the certification requirement that it took for applying the transitional risk reinsurance fee to the large universe of health plans. The ACA directed HHS to develop the method for determining the amount of the transitional reinsurance fee that health insurance issuers and group health plans were required to pay. In its regulations interpreting this provision of the ACA, HHS limited the fee so that health plans are only subject to the fees with respect to each covered life that is enrolled in major medical coverage and not to the myriad of smaller “add-on” plans and benefits. “Major medical coverage” is generally defined as health coverage for a broad range of services and treatments provided in various settings. As a result, the fee does not apply to other types of medical benefits, including most employee assistance programs (“EAPs”) and other excepted benefits.

Similarly, HHS has focused on major medical plans with respect to the penalty for noncompliance. The proposed regulations provide health plans must disclose to HHS the number of “covered lives” of a CHP.
major medical policies…” The term “major medical policy” is defined as “an insurance policy that covers accident and sickness and provides outpatient, hospital, medical and surgical expense coverage.” The provision limiting the penalty to major medical policies is consistent with the statute, which provides that the penalty “shall be assessed per person covered by the plan for which its data systems for major medical policies are not in compliance.” Accordingly, a health plan that does not offer major medical coverage is effectively exempt from the certification requirement, since the plan will owe no penalty for noncompliance.

ERIC urges HHS to apply the substantive certification requirement, as well as the penalty for noncompliance, only to major medical plans, which handle the vast majority of workers’ medical claims. Programs that provide only limited health benefits, such as EAPs and excepted benefits, should not be subject to these onerous rules. HHS should adopt the same approach for the proposed regulations that it used for the transitional reinsurance fee.

IV. The proposed regulations should clarify that a plan is subject to the certification requirement only to the extent that it provides or arranges for the provision of medical care.

The statutory certification requirement applies to “health plans,” a term that includes most group health plans with 50 or more participants. For this purpose, HHS’s regulations define a “group health plan” as an employee welfare benefit plan within the meaning of section 3(1) of ERISA, but only “to the extent that the plan provides medical care.”

Under ERISA, plan sponsors have significant latitude in determining which benefits are included in their employee welfare benefit plans. Some plan sponsors use a document that includes a variety of different benefit programs (known as a “wrap plan document”): the welfare plan might include some programs that provide medical care and others that do not. For example, the wrap plan document might include major medical, dental, disability, and life insurance benefits. The programs may be treated as one plan for ERISA’s reporting and disclosure requirements.

ERIC urges HHS to clarify that an employee welfare benefit plan is subject to the certification provisions only to the extent that the plan provides or arranges for the provision of medical care. For example, a welfare benefit plan should not be required to certify that it meets the HIPAA transaction standards when it conducts electronic transactions relating to disability benefits, life insurance benefits, or other non-medical benefits.

V. The proposed regulations should clarify that a plan will be considered a controlling health plan consistently with the manner in which it is determined for ERISA purposes.

The proposed regulations’ requirements apply to each “controlling health plan”, which is generally defined as a health plan that controls its own business activities. HHS regulations provide that the term “health plan” includes a “group health plan”, which is defined by reference to ERISA.

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17 Social Security Act § 1173(j)(1)(B) (emphasis added).
18 45 C.F.R. § 160.103 (emphasis added).
19 HHS Reg. § 160.103.
Many large employers offer a group health plan that includes a number of different benefit options. For example, a group health plan might offer a high-deductible option, a low-deductible option, and an HMO option. As long as the employer documents and administers these different benefit options as a single group health plan, the arrangement is treated as a single plan for purposes of ERISA.

ERIC urges HHS to clarify that that a plan will be considered a controlling health plan consistently with the manner in which it is determined for ERISA purposes. If a number of different health benefit options are part of a single group health plan under ERISA, the arrangement should be treated as a single controlling health plan for purposes of the certification requirement: HHS should not require each benefit option under a group health plan to certify separately that it complies with the HIPAA transaction standards.

VI. The rules should be clarified to take into account the special nature of self-insured plans.

A. HHS should clarify that the number of individuals used to calculate the penalty should be based only on the number of individuals covered by or enrolled in insurance policies that are major medical policies.

The proposed regulations would require plans to notify HHS about the number of persons covered by an insurance policy, which could be used as the basis for assessment of any penalty. Proposed HHS Regulation § 162.926 states that health plans must disclose to HHS the number of “covered lives” of a CHP. Proposed HHS Regulation § 162.102 states that the “covered lives of a CHP” means “individuals covered by or enrolled in major medical policies…” Proposed HHS Regulation § 160.604 defines “major medical policy” as “an insurance policy that covers accident and sickness and provides outpatient, hospital, medical and surgical expense coverage.”

Self-insured plans by definition do not include individuals covered by or enrolled in insurance policies that cover accident and sickness or that provide outpatient, hospital, medical and surgical expense coverage. Sometimes an employer that predominantly offers self-insured coverage will also offer HMO coverage to individuals in certain geographic locations, but the HMOs will typically cover only a small fraction of the employer’s employees. Thus, the proposed regulations indicate that no penalty would apply with respect to most participants in self-insured plans because these participants would not be covered by insurance policies; the penalty, if any, would be based only on the employees of the employer enrolled in fully-insured HMOs or other insured policies.

ERIC urges HHS to confirm that the number of individuals used to calculate the penalty for failing to comply with the proposed regulations’ reporting requirements is based only on the number of individuals covered by or enrolled in insurance policies that are major medical policies. As explained above, this interpretation is consistent with the statutory language, which provides that the penalty “shall be assessed per person covered by the plan for which its data systems for major medical policies are not in compliance.”

20 Social Security Act § 1173(j)(1)(B) (emphasis added).
B. The number of covered lives to be provided to HHS should be as of a prior fixed date, rather than the date that the required documentation is submitted.

The proposed regulations provide that plans must provide the number of covered lives of a CHP on the date that the required documentation is submitted.

The number of covered lives in a health plan fluctuates from day to day for a variety of reasons. Employees join and leave the plan, cease to be covered during leaves of absence or periods of part-time work, or transfer to different business units that maintain separate health plans; new dependents are born; and covered individuals die. It will not be possible for an employer to determine the number of covered lives in a large health plan (which might cover tens of thousands of individuals) on the date when the employer submits the documentation to HHS, since the number of covered lives will change while the employer is performing its headcount. Even if an employer were able to determine the number of covered lives on the date of the submission, the information would be out of date as soon as HHS received it. Accordingly, requiring a contemporaneous headcount imposes a substantial burden on the employer with no corresponding benefit to HHS.

ERIC urges HHS to provide that the number of covered lives should be determined as of a prior fixed date selected by the employer and communicated to HHS, such as the first day or the last day of the most recent completed plan year, rather than the date that the required documentation is submitted.

C. HHS should request that CAQH clarify that self-insured plans will be treated similarly to government entities for fee purposes.

The preamble to the proposed regulations indicates that CAQH charges entities a fee based on net annual revenue. The preamble also indicates that “because government entities do not generate net annual revenues, they have been included in the 5 percent computation of CHPs with net annual revenues less than $5 million.” Plans in this category are only required to pay a fee of $100 for the HIPAA credential.

Like government entities, self-insured plans do not generate net annual revenue. These plans do not generate any net revenue, but instead incur expenses for the provision of benefits to those covered by the plan. As a result, HHS should request that CAQH clarify that self-insured plans will be treated similarly to government entities as having net annual revenues of less than $5 million and therefore are required to pay only the fee of $100 for the HIPAA credential.

D. HHS should not require attestation forms for self-insured plans.

The proposed regulations require a senior level executive for a controlling health plan to sign an attestation form that the plan complies with HIPAA’s security, privacy, and transaction standards.
Pursuant to ERISA, a self-insured plan is a separate legal entity from the plan sponsor. Self-insured plans typically do not have senior level executives. Instead, the plan is administered by plan fiduciaries who often are employed by the plan sponsor and not the plan. Self-insured health plans are covered entities under HIPAA and, as such, are required to appoint a Privacy Officer.

Furthermore, as explained above, most self-insured plans do not handle Covered Transactions. The vendors that handle these transactions on behalf of the plan are in a better position to attest to the plan’s compliance with HIPAA for Covered Transactions.

As a result, ERIC urges HHS to exempt self-insured plans from the requirement that a senior level executive for a plan sign an attestation form on behalf of the plan.

**E. HHS should modify the proposed regulations to eliminate the requirement that plans certify compliance with HIPAA’s security and privacy standards.**

The ACA provides that health plans must file a statement with HHS certifying compliance with the transaction standards. However, the proposed regulations require a senior level executive for a controlling health plan to sign an attestation form that the plan complies not only with HIPAA’s transaction standards, but also with HIPAA’s security and privacy standards.

There is no statutory basis for a requirement that group health plans certify compliance with HIPAA’s security and privacy standards. ERIC urges HHS to modify the proposed regulations to eliminate this requirement.

**F. The proposed regulations should be re-proposed and the deadline extended.**

Plan sponsors have limited resources that can be devoted to addressing the multitude of new requirements for their health plans. They have been actively working for the past several years, and will continue to devote significant time and resources over the next several years, to comply with all of the requirements imposed by the ACA. For example, companies are actively working to design and implement systems to comply with recent regulations that impose new reporting and disclosure and employer shared responsibility requirements.

The additional burdens imposed by the proposed regulations are particularly problematic for self-insured plans. As discussed above, self-insured plans have numerous questions and concerns as to the manner in which the proposed regulations would apply to them.

Furthermore, the proposed regulations fail to define or provide a standard for the “end-to-end testing” required for certification. The preamble to the proposed regulations states “the meaning of the phrase ‘end-to-end testing’—as well as the types of testing necessary for successful transitions to new or revised standards, code sets, or operating rules—is presently the subject of active discussion in the health care industry.”

Given the lack of guidance in the proposed regulations, it is difficult to provide meaningful feedback as to the areas that need clarification. If HHS insists on maintaining the current structure of

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24 ACA §1104.
25 Id. at 308.
26 79 Fed. Reg. at 310.
the proposed regulations, then ERIC urges HHS to re-propose the regulations with language that clearly reflects the manner in which these requirements would apply to self-insured plans, if at all, and the standard for “end-to-end testing”; and provide for an extended deadline for compliance.

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ERIC appreciates the opportunity to provide comments on the proposed regulations. If HHS has any questions concerning our comments, or if we can be of further assistance, please contact us at (202) 789-1400.

Sincerely,

Scott J. Macey
President & CEO

Debra A. Davis
Vice President, Benefits
Exhibit A – Insured and Self-Insured Plans

Most companies generate revenue by providing or distributing goods and/or services (the “Goods/Services Companies”) that are completely unrelated to the provision of health benefits. The following description summarizes the typical fully-insured and self-insured arrangements for the provision of health benefits by Goods/Services Companies to workers.

Fully Insured Plans

Some Goods/Services Companies provide health benefits to their workers through fully insured plans offered by insurance companies. Under this approach, the Goods/Services Company pays a fixed amount (i.e., a premium) per month per employee (or per family), and the employee and any family members receive the benefits provided under the plan.

The insurance company will provide the Goods/Services Company with a plan document that describes which employees are covered by the plan, the health benefits that will be provided, and the cost for that coverage. The Goods/Services Company will typically have employees complete paperwork if they are eligible to participate in the plan. The Goods/Services Company also withholds the employees’ portions of the premiums from their paychecks and sends it with the Goods/Services Company’s own contribution to the insurance company.

The insurance company typically contracts directly with providers, including doctors, hospitals and pharmacies, to provide benefits to the participants in the plan. The insurance company also pays these providers directly for their services.

The insurance company bears the risk of loss. That is, if the cost of the benefits provided is less than the amount of the premiums, the insurance company retains the amount as profit; if the cost of the benefits exceeds the amount of the premiums, the insurance company will suffer a loss for that employer’s plan.

Self-Insured Plans

Some Goods/Services Companies self-insure their plans. In a self-insured plan, the Goods/Services Company bears the risk for unusually high costs for the plan. Most large employers self-insure their plans.

The Goods/Services Company will typically have an attorney draft a plan document that describes which employees may be covered by the plan, the health benefits that will be provided, and the cost for that coverage. Thus, the “plan” is merely a document that was created for the plan sponsor. Pursuant to ERISA, the plan is a separate legal entity from the Goods/Services Company. The plan document will usually name plan fiduciaries who are responsible for the plan and who can sign contracts on behalf of the plan.28

27 For ease of reference, the terms “employee” and “worker” will be used to refer to both employees and their family members.
28 Plan fiduciaries often work for the Goods/Services Company in a leadership capacity and are responsible for making sure that the plan is being operated in accordance with its terms. Thus, plan fiduciaries will typically review the contracts with vendors and/or arrange for experts to assist them.
The Goods/Services Company typically has contracts with the vendors. In these contracts, the vendors agree to comply with HIPAA.

All the work related to the provision of benefits is typically performed by vendors hired by the fiduciaries. The fees for these vendors is often paid by the Goods/Services Company. These vendors will determine eligibility and answer workers’ questions. Other vendors will arrange for the provision of health services to the participants in the plan through contracts with providers, including doctors, hospitals and pharmacies. The Goods/Services Company generally does not have any direct contracts with the providers and may not even be able to review the contracts that the vendors have with the providers. The vendors pay these providers directly for their services.

Vendors generally require the Goods/Services Company to transfer funds to it on a regular basis. These payments are often made from the Goods/Services Company’s general assets and typically are made daily for major medical plans. The Goods/Services Company may also require workers to contribute towards the cost of the plan and will withhold pre-determined amounts from employees’ paychecks for this purpose. The vendors use the funds received from the Good/Services Company to pay the providers.

The Goods/Services Company bears the risk in these plans. That is, the cost to the Goods/Services Company to provide benefits to the employees depends on the amount of the claims. If workers are healthier in a year and use fewer health services, then the Goods/Services Company’s costs for the plan will be lower than in a year when workers use more health services.

The plan sponsor, which is not a covered entity under HIPAA, typically provides information directly to the plan’s vendors. These vendors use that information to administer the plan and provide benefits to participants.