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February 28, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-0037-P
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Administrative Simplification: Certification of Compliance for Health Plans; Proposed Rule [CMS-0037-P]

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), we appreciate the opportunity to comment on the proposal entitled, Administrative Simplification: Certification of Compliance for Health Plans [CMS-0037-P]. The AMA believes that a strong health plan certification process is necessary to ensure the benefits and cost savings of administrative simplification. This proposed rule provides an initial step towards guaranteeing uniformity in data exchange between controlling health plans (CHPs) and providers; however, we believe that the certification process falls short in a number of ways and could be strengthened, as identified below.

Scope of Certification

Section 1104 of the Patient Protection and Affordable Care Act requires applicable health plans to certify compliance with both standards and the associated operating rules for identified transactions. This requirement recognizes that both parts are essential for the successful use of electronic transactions—the standards prescribe the data content and format of an electronic transaction, while the associated operating rules address specific business criteria, including connectivity requirements and response time, not addressed by the standards. Yet, the two documentation avenues proposed in the rule address compliance primarily with the operating rules, not standards. Since there are far more data requirements in the standards than the operating rules, this omission could allow a CHP to essentially fail to meet standard specifications yet still pass certification. While the statute provided some guidance on the submission requirements to achieve certification, these are merely a floor upon which the regulations should build an adequate certification system. **We therefore encourage the Department of Health and Human Services (HHS) to require documentation of compliance with both standards and operating**

rules. In addition, we believe an entity with expertise in HIPAA standards, and not primarily operating rules, should play a role in the certification process.

Further, to achieve full end-to-end administrative simplification, the rule should not limit its scope to CHPs but should address practice management system (PMS) vendors, third-party administrators (TPAs), electronic health records (EHRs), and clearinghouses. The Council for Affordable Quality Healthcare Committee on Operating Rules for Information Exchange (CAQH CORE) already includes PMSs and clearinghouses in its voluntary certification process, recognizing their essential role with payers and providers. In addition, many self-insured plans contract out administrative simplification functions so that TPAs are the actual entities that carry out standard transactions. We believe that including these entities in the certification process is necessary to ensure that electronic transactions are more predictable and consistent across all parties.

Snapshot Evaluation and Enforcement

HHS is proposing that the submission requirements only capture CHPs' compliance at a particular point in time rather than allow for continued verification. We believe this approach offers no guarantee of future compliance, as CHPs will not be required to regularly update or resubmit documentation. There is also no intent to track CHPs that lose Phase III CORE Seal Certification, and there is no mechanism for physicians to discern a CHP's certification status. This essentially leaves providers with no notice or future assurance that transactions will be carried out according to the standards and operating rules. **The AMA is concerned that this proposed approach will provide little incentive for plans to maintain compliant processes beyond the initial date of certification.**

This concern is further exacerbated by the proposal for penalty caps, which will only be assessed for the first 20 days of noncompliance and is unlikely to be a sufficient financial deterrent for CHPs. This limited penalty structure removes any incentive for a noncompliant CHP to meet certification requirements in the future. In contrast, the statute contemplated that penalties be assessed annually and be increased on an annual basis; however, these requirements are absent in the proposed rule.

Similarly, although audits are explicitly mentioned in the statute, the proposed rule does not address the process or scope of audits. This omission further weakens the proposed certification process, leaving no authority to guarantee ongoing compliance. **The AMA understands that the penalty provisions and amounts are controlled by statute; however, we believe that HHS can use the submission requirements, penalties, and audit process in ways that urge plans to become and remain compliant over time.** We also believe that plans should be audited on an unannounced basis to ensure they are maintaining compliance. Further, we believe that if users or those representing users highlight a specific complaint with regard to a plan the certification and audit process should consider these concerns and guarantee that problems are addressed and resolved in a timely manner.

HHS should also publish or otherwise readily provide CHPs certification information to providers. This would serve as a deterrent to CHP noncompliance while also alerting physicians of concerns with any CHPs with whom they may contract. **We strongly urge HHS to publish a list of CHPs that are and are not in compliance with the certification requirements, or, at the very least, make this information available upon request.**

Furthermore, we believe that any period of noncompliance can be disruptive to providers. The AMA therefore supports the proposal that CHPs cannot be under a CAQH CORE certification exemption at the time of certifying compliance. However, we believe that this cannot be the only check on CHPs and urge HHS to develop a certification process that guarantees ongoing compliance.

HIPAA Credential

We appreciate HHS' effort to offer flexibility to CHPs by providing two options in how to document certification; however, we have several concerns with the proposed HIPAA Credential. Based on the Notice of Proposed Rulemaking's description, we caution that the HIPAA Credential will not require testing with a third-party testing vendor, which we believe to be essential to ensure an unbiased evaluation. Additionally, although the rule references each, it does not feature an explicit definition or any prescribed level of what is meant by "successfully tested" or who is considered a "trading partner."

With the HIPAA Credential still under development, we believe it imprudent to recommend a credentialing option without possessing adequate details concerning the process. Furthermore, it is hard for the industry to provide meaningful comment when we do not yet know what the process is expected to look like. As the less expensive approach, we believe that many CHPs may choose the HIPAA Credential over the CORE Seal. **Therefore, we believe that the HIPAA Credentialing process should be fully developed and subject to public comment and subsequent editing before it is recognized as an acceptable compliance certification option.**

The AMA is also concerned that the same organization, CAQH CORE, will be administering both proposed submission choices. This limits stakeholder involvement and discourages other entities from developing ways to improve the accreditation process in the future. This also leaves HHS without a certification body should CAQH CORE at some point in the future be unable to meet the obligation of certifying all CHPs or divest from the certification business. Instead, HHS may wish to encourage diversity by allowing other entities to participate in the certification process. **We believe that the final regulation should include language that allows for additional certification bodies to be named in the future and a review process to identify additional certification bodies.**

Demonstrating End-to-End Testing

HHS acknowledges that the lack of a consistent testing process has hindered implementation of administrative simplification requirements in the past, yet in the proposed rule it fails to define or require compliance with the "end-to-end testing" mandated by statute. To fill this significant gap, the AMA recommends that HHS adopt the definition of "end-to-end testing" used by the National Government Services pilot testing project, which defines the term as "a focused process within a defined area, using new or revised applicable products, operating rules or transactions, throughout the entire business and/or clinical exchange cycle, for the purpose of measuring operational predictability and readiness. The end-to-end testing process should be performed in an environment which mirrors actual production as closely as possible, confirming the validation of performance metrics and analytics (reporting)."¹ Establishing an explicit definition will ensure that CHPs demonstrate satisfactory and consistent end-to-end testing for

¹ NGS, Pilot for End-to-End Testing of Compliance with Administrative Simplification
<http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/AffordableCareAct/NGSRound2ListeningSessionPilotforEndtoEndTestingofCompliance2113.pdf>.

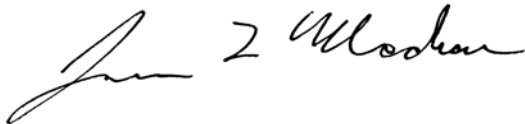
compliance certification. Further, if the December 2015 deadline is maintained, this will give the industry ample time to develop processes needed for completing end-to-end testing.

Timing

According to the statute, health plans were intended to meet certification for the first sets of standards and operating rules by December 2013 and the second sets by December 2015. The proposed rule pushes the 2013 compliance date back by at least two years, stating that CHPs will complete the certification process by December 31, 2015, at the earliest. However, plans are **already required** to be in compliance with these standards and operating rules under previous regulations. CHPs should not need two years to document compliance with requirements already in effect. **If the proposed rule's December 2015 deadline is maintained, CHPs should also be required to certify compliance with the additional mandated standards and operating rules, including health care claim or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health claim attachments and referral certification and authorization.** Otherwise, health plans will again fail to meet statutory deadlines and will continue to slow down the movement towards administrative simplification.

Overall, the AMA seeks to ensure that the certification process can verify that plans are appropriately using standards and operating rules. A valid certification process can improve efficiency and provide significant savings for the health industry. The AMA looks forward to a continued dialogue on creating and implementing such a certification process. If we can be of any further assistance, please contact Mari Savickis, Assistant Director, Federal Affairs, at (202) 789-7414 or mari.savickis@ama-assn.org.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is fluid and cursive, with a large initial "J" and a distinct "M".

James L. Madara, MD