

July 25, 2013



Ms. Susan McAndrew  
Deputy Director for Health Information Privacy  
Office for Civil Rights  
Department of Health and Human Services  
200 Independence Avenue, SW  
56E 5<sup>th</sup> Floor  
Washington, D.C. 20201

RE: HIPAA Omnibus Rule: Clarification Sought on Marketing Rule Changes

Dear Ms. McAndrew,

This letter is submitted by the Specialty Pharmacy Association of America (SPAARx) on behalf of our national membership.

The Specialty Pharmacy Association of America (SPAARx) is the largest, free-standing, national organization representing the specialty pharmacy industry with more than 3,500 individual members. SPAARx was launched in response to a clear call from specialty pharmacies, specialty pharmaceutical manufacturers, payers and other organizations to form a self-governing, national association that broadly represents the professional and personal interests of all specialty pharmacy industry stakeholders. SPAARx's mission is to protect and promote interests common to the specialty pharmacy industry, foster professional growth, and sustain the development and success of specialty pharmacy nationally.

This letter addresses sponsored patient messaging about current prescription, including refill reminders and compliance & persistency interactions and the changes found in the U.S. Department of Health and Human Services' (HHS) newly issued revisions to HIPAA regulations that implement the HITECH Act. 78 Fed. Reg. 5566 (Jan. 25, 2013) ("final rule").

#### CLARIFICATION SOUGHT

The Specialty Pharmacy Association of America respectfully recognizes HHS's intent to strengthen consumer privacy and data security protections, and enhancing enforcement for HIPAA violations by covered entities and their business associates; however, a number of questions are left unresolved and potentially conflict with the best healthcare practices for compliance and persistency programs developed and implemented by specialty pharmacies to enhance quality of patient care through proactive compliance programs.

In particular, SPAARx is concerned that certain language in the final rule regarding the statutory exception for "refill reminders." will be misinterpreted and could seriously impede medication adherence programs with no substantive benefits to patient privacy. As such, SPAARx seeks that HHS clarify these issues in guidance or FAQs. Given that the revisions will go into effect in less than ninety (90) days, SPAARx encourages the Department to act swiftly to address these concerns.

Specifically, SPAARx seeks to have the Department clarify its position on the definition of marketing to resolve instances where the covered entity receives direct or indirect remuneration in exchange for making communications with patients, specifically compliance and persistency services including refill reminders as referenced in the Omnibus Rule. Additionally, costs related to delivering enhanced therapy management services should be allowable for a broad range of refill reminders and related

communications about a drug or biologic currently prescribed or expired. As currently defined, the Department is limiting remuneration to the specific direct cost of making the communication (e.g., drafting, printing, mailing), which does not fairly recognize the additional expenses of clinicians and staff that deliver therapy management traditionally telephonically.

SPAARx would suggest that the Department considers using 'Fair Market Value' as a guideline for remuneration. Fair Market Value provides a consistent and uniform measure as expressed by HHS's Office of Inspector General which has previously recognized that sponsored programs of healthcare providers are generally not of anti-kickback enforcement concern provided that the payments do not exceed Fair Market Value of any legitimate service rendered to the sponsor. Not only would the use of a Fair Market Value as a standard to determine the "reasonableness" of the remuneration allow for the healthcare improvements available through better adherence and compliance of patients, it also permits alignment of healthcare provider's compliance programs to ensure that compliance with the Privacy Rule does not create non-compliance with anti-kickback obligations.

Further, we encourage the Department to review its restrictions on the use of patient contact lists and other marketing using PHI especially as it relates to the use of mobile devices and social media. The current language is inconsistent with emerging methods of physician – pharmacy - patient communication that is designed to enhance the care team concept integral in new best practices.

Lastly, SPAARx requests further clarification of how penalties will be assessed for violations once any adjustments to the rules are issued.

#### CONCLUSION

The Accountable Care Act was passed by Congress for a number of reasons including a proactive movement towards Medication Therapy Management. Congress clearly sought to protect and enhance public health benefits that accrue to patients through adherence and compliance messaging programs. Unfortunately, the current interpretation of HITECH through the HIPAA Omnibus rule impacts these potential benefits. We respectfully urge the Department to issue clarification (such as in a guidance or FAQ) on the points discussed above. The Department should do so as soon as reasonably possible so as not to hinder refill reminder programs after the September 23, 2013 compliance date of the final rule. We welcome an opportunity to discuss the issues raised by this letter with you and your staff in person.

We appreciate the Department's consideration of this request.

Respectfully submitted,



William J Sullivan  
Executive Director  
Specialty Pharmacy Association of America