



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

August 9, 2013

RE: Specialty Pharmacy Association of America Letter of July 25, 2013

Dear Ms. McAndrew:

The World Privacy Forum is a non-profit public interest research group. We focus on conducting in-depth privacy research and consumer education in the public interest. One of our major issue areas is health privacy, and as such, we monitor developments in this area closely.

We feel obliged to write to you on behalf of consumers in response to the Specialty Pharmacy Association of America's letter of July 25, 2013.

We will be direct. We believe that SPAARx wants HHS to change the HIPAA privacy rule to increase marketing uses of Protected Health Information (hereafter PHI) and to enhance the profitability of refill reminder programs for its members. We strongly oppose those changes for both procedural and substantive reasons, which we outline in this letter.

First, HHS just amended the HIPAA privacy rule, with the amendments set to take effect in a few weeks. We are generally happy with the new amendments, although not all of the changes we asked for were included. We were grateful for the opportunity to comment on the rule, and we accept the revised rule. We will, at the appropriate time, seek further privacy protections for consumers.

SPAARx had its chance to comment, but it now wants the rule revised further. SPAARx asks for more guidance in its letter, but what it seeks cannot be accomplished in guidance. Only an amendment to the rule itself could achieve the results SPAARx wants. It is legally impossible for HHS to comply with SPAARx's request without changing the rule, and we do not believe that it is possible or appropriate to reopen the rule to change at this late date.

Second, SPAARx's substantive objectives are inconsistent with the existing regulation and with the HITECH Act as well. Congress looked very specifically at the prescription reminder issue, and intentionally decided to allow refill reminder programs with a strict limit on the reimbursement of costs. Congress did not want the refill reminder programs to become major profit centers for pharmacies, and Congress purposefully did not allow any broader marketing uses of PHI. The Department has revised the rule in accordance with the statute, and the Department provided a reasonable definition for the financial remuneration allowable for refill reminder programs. The preamble to the final rule offers useful guidance. There is no need or justification for any changes now.

Third, SPAARx wants further unspecified changes having to do with use of mobile devices and social media for physician-pharmacy-patient communications. The privacy rule already allows all appropriate communication from a health care provider to a patient. With a patient's consent, a provider can make those communications via a mobile device. There is no need for any clarification here. We believe that SPAARx's request is another stalking horse for making marketing communications that the rule properly bans.

We observe that prescription refill reminder programs are often only available for high-priced, patent-protected drugs. Reminders are often sent primarily when the programs are profitable to pharmaceutical manufacturers and to pharmacies. Whether there is any patient benefit is uncertain. Congress allowed for appropriate reminders to benefit patients; Congress understood that drug manufacturers and pharmacies are often key beneficiaries of the programs. Therefore, HITECH does not allow the programs to operate without appropriate constraints, checks, and balances.

There is no question that manufacturers and pharmacies would be happy to find new ways to use social media and other new mechanisms to increase opportunities to use PHI to market to patients in order to enhance profits. But the rule allows this flexibility with express patient consent. That is the right result. SPAARx is working to convince the Department to allow more marketing, rather than to convince patients who generally do not want to be the targets of health care marketing.

We have great confidence that the Department will do the right thing and reject the request of SPAARx.

Respectfully submitted,



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