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Q&A With Alston & Bird's Paula Stannard

Law360, New York (September 06, 2011, 1:50 PM ET) -- Paula Stannard is counsel in the Washington, D.C., office of Alston & Bird LLP. She is a former deputy general counsel and acting general counsel of the U.S. Department of Health and Human Services, where she oversaw the general counsel's food and drug, civil rights and legislation divisions. Now, Stannard advises clients on regulatory questions that arise out health care reform and focuses her practice on the Health Insurance Portability and Accountability Act and health information technology, food and drug, and other regulatory issues in the health care sector.

Q: What is the most challenging case you have worked on and what made it challenging?

A: Without question, the most challenging case I worked on in the privacy area was one of the cases I worked on while I was at HHS, South Carolina Medical Association v. Thompson, challenging the constitutionality of HIPAA and the HIPAA Privacy Rule on the basis of the nondelegation doctrine and the due process clause, and claiming that HHS exceeded its statutory authority in regulating all forms of health information, not just electronic health information.

Although the U.S. Supreme Court has not struck down a statute as containing an impermissible delegation of congressional authority since Schechter Poultry and Panama Refining, HHS promulgated the lengthy Privacy Rule based on a several-line subsection in HIPAA (§264(c)) that is not even codified in the U.S. Code. As a government lawyer, I did not want to work on the first case since 1935 in which a statute is struck down for violating the nondelelgation doctrine — especially when my boss, the general counsel of HHS, decided to argue the case in the Fourth Circuit!

Part of the challenge was §264. It required HHS to make recommendations to Congress on standards for protecting health information, including the rights an individual should have with respect to their health information, how those rights should be exercised, and the uses and disclosures of health information that should be authorized or required. If Congress didn't enact a statute establishing standards

for health information privacy within a certain period, HHS was to do so by regulation.

In arguing that HIPAA provided an "intelligible principle" to govern HHS's exercise of authority, we convinced the Fourth Circuit to look not only at what §264 said about the scope of HHS's regulatory authority, but also at what the other HIPAA administrative simplification provisions said about the purpose of the statute and regulation, the entities subject to regulation, the scope of information to be protected, the penalties to be imposed for violations of HIPAA, the timelines and standards for compliance, and the preservation of certain public health and state regulatory reporting activities. We were, thus, able to convince the Fourth Circuit that HIPAA provided an "intelligible principle" for HHS to follow — and, consequently, that HIPAA and the Privacy Rule were constitutional.

Q: What aspects of your practice area are in need of reform and why?

A: Although the Office for Civil Rights has done its best to promptly implement the changes to the HIPAA rules required by the Health Information Technology for Economic and Clinical Health Act and other statutes — and was recently charged with implementing and enforcing the Security Rule — the practice area is currently in a state of uncertainty because of delay in promulgating those final rules. In some cases, this means that issues have to be analyzed under two or three different regulatory scenarios. So, final rules are needed.

Beyond that, it would be helpful if OCR reformed the manner in which it issues guidance. Many of the guidance materials and FAQs on OCR's website are dated and will need to be revised, updated and/or expanded based on the changes in the regulations. It would also be helpful if guidance issued in the form of responses to individual letters or emails were added to the website so that it is more readily available to all practitioners.

Q: What is an important case or issue relevant to your practice area and why?

A: HHS/OCR's approach to compliance, enforcement and compliance audits is an important issue in health privacy.

OCR is drafting the final rule to implement changes in the regulations pursuant to the HITECH Act, including provisions for the direct regulation and liability of covered entities' business associates (and, if finalized as proposed, business associates' subcontractors). OCR may also promulgate changes to the Breach Notification Interim Final Rule that may eliminate or significantly reduce the ability of covered entities (and their business associates) to determine, based on a risk assessment, that an incident involving the improper access, use, or disclosure of protected health information does not constitute a breach for which notification is required.

As OCR finalizes these substantive changes to the privacy, security and breach notification rules, the changes in the enforcement environment that signal a more aggressive approach to enforcement are going to take on additional significance. On the statutory side, the HITECH Act significantly increases the amount of civil money penalties (CMPs) that can be imposed per violation and in the aggregate per type of violation per year; lowers the substantive threshold for imposing CMPs; permits OCR to retain the CMPs and monetary settlements it collects to fund further enforcement efforts; authorizes state attorneys general to enforce the rules in federal court; and requires OCR to implement a compliance audit program to audit compliance with the HITECH Act and the privacy and security rules.

On the regulatory side, proposed changes to the HIPAA Enforcement Rule would, among other things, no longer require OCR to attempt informal resolution of complaints; and in determining the amount of a CMP, would permit OCR to consider not only past confirmed "violations" of the Privacy or Security Rules, but also "indications of noncompliance."

And OCR has recently begun to implement a compliance audit program by awarding contracts to one consulting firm to apparently identify audit candidates and to another firm to develop an audit protocol and, under its guidance, to conduct up to 150 audits by December 2012. All of these changes increase the potential exposure of covered entities and their business associates (and business associate subcontractors) in the event of a potential violation of the HIPAA Privacy, Security, or Breach Notification Rules.

Q: Outside your own firm, name an attorney in your field who has impressed you and explain why.

A: Carol Conrad, a former career staff attorney at HHS. Her knowledge of HIPAA was encyclopedic. Her ability to draft and defend difficult or controversial regulations or regulatory provisions — honed over a career at HHS — served HHS well with all of the HIPAA regulations, but especially with respect to the Privacy and Enforcement Rules.

Q: What is a mistake you made early in your career and what did you learn from it?

A: Early in my career, I permitted my work to take over my life, to the exclusion of most outside activities. I have gradually attempted to establish a better work/life balance — and now actively pursue several hobbies, am involved in several organizations, and teach CCD at my church during the school year. I've learned that taking time for me makes me a more rounded individual, enables me to see issues from other perspectives, and permits me to return to my work with a fresh outlook. But it is a constant struggle to maintain that balance.