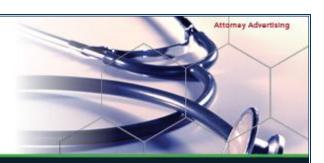
Robinson+Cole

Health Law Pulse



November 2014

In This Issue

- Connecticut Supreme Court: HIPAA Does Not Preempt Negligence Claims
- CMS Removes Continuing Education Exemption to Physician Payments Sunshine Act
- Federal Government and New York Reject Mount Sinai's 60-Day Rule Arguments

CONNECTICUT SUPREME COURT: HIPAA DOES NOT PREEMPT NEGLIGENCE CLAIMS

The Connecticut Supreme Court recently held that the Health Insurance Portability and Accountability Act of 1996 (HIPAA) does not preempt state law negligence claims in connection with a health care provider's alleged breach of a patient's confidentiality. The decision *Byrne v. Avery Center for Obstetrics and Gynecology, P.C.*, 214 Conn. LEXIS 386 (Conn. 2014), reversed a trial court decision that had dismissed claims for negligence and negligent infliction of emotional distress on the basis that such claims were preempted by HIPAA. The Supreme Court reversed the trial court's preemption finding and further held that in certain circumstances HIPAA can inform the applicable standard of care for a negligence action in Connecticut.

The underlying dispute in *Byrne* involves plaintiff Emily Byrne's medical records held by defendant Avery Center for Obstetrics and Gynecology (Avery Center). Ms. Byrne, who had received obstetrical and gynecological care from Avery Center, instructed the Avery Center staff not to disclose her medical records to her former partner. In connection with a paternity suit, the former partner subpoenaed Ms. Byrne's medical records from Avery Center. Upon receiving the subpoena, Avery Center mailed copies of Ms. Byrne's medical records to the courthouse without first making any attempts to notify Ms. Byrne or quash the subpoena, in direct violation of Ms. Byrne's explicit instructions. Once in the custody of the court, Ms. Byrne's medical records were made available to her former partner. Ms. Byrne and her family.

Ms. Byrne filed suit against Avery Center, alleging negligence and breach of contract in connection with the release of her medical records. The trial court dismissed claims of negligence and negligent infliction of emotional distress on the basis that HIPAA does not confer a private right of action and that HIPAA preempts state law claims that amount to HIPAA violations, unless such claims are brought under a more stringent state law governing the conduct in question. Under HIPAA, a state law is generally considered "more stringent" if it provides greater privacy protection for individuals' health information than exists under HIPAA.

The Supreme Court held that a state law claim is not preempted by HIPAA solely because it imposes additional liability. The Supreme Court held that allowing state law negligence claims based on HIPAA violations serves to support HIPAA's goal of protecting the privacy of medical records and is therefore consistent with the regulatory intent behind HIPAA's preemption provision. The Supreme Court noted that state law negligence claims create a disincentive to wrongfully disclose private medical records, consistent with HIPAA's goals. The Supreme Court further held that, to the extent it has become common practice for Connecticut health care providers to comply with HIPAA, HIPAA's regulations can inform the necessary standard of care for such negligence claims in Connecticut.

While the *Byrne* decision apparently exposes health care providers to increased liability under Connecticut law for HIPAA violations, the Supreme Court declined to rule on whether Connecticut actually recognizes a cause of action for negligence in connection with a health care provider's breach of its duty of confidentiality related to its furnishing of a patient's medical records to a court in response to a subpoena. As a result, the scope of the Supreme Court's ruling, including its application to Ms. Byrne's own case, is uncertain, and further litigation may be necessary to determine the full impact of this decision.

CMS REMOVES CONTINUING EDUCATION EXEMPTION TO PHYSICIAN PAYMENTS SUNSHINE ACT

The Centers for Medicare & Medicaid Services (CMS) recently released a <u>final rule</u> (Final Rule) that revises payment policies for services furnished under the Medicare Physician Fee Schedule. The Final Rule removes an exemption to the Physician Payments Sunshine Act's (Sunshine Act) reporting requirements for payments to physicians and teaching hospitals (Covered Recipients) associated with continuing education events.

The Sunshine Act requires manufacturers of covered drugs, devices, biologicals, and medical supplies to submit annual reports to CMS on certain payments or other transfers of value made to Covered Recipients. When first implemented in 2013, the Sunshine Act included an exemption (Continuing Education Exemption) for payments or other transfers of value provided as compensation for speaking at a continuing education event. The Continuing Education Exemption applied only where (1) the continuing education event met the certification requirements and standards of one of five continuing education organizations specifically listed in the Sunshine Act; (2) the manufacturer did not pay the Covered Recipient directly; and (3) the manufacturer did not select the Covered Recipient or furnish the continuing education provider with a distinct, identifiable set of individuals to be considered as speakers for the continuing education event. Following the initial implementation of the Sunshine Act, various stakeholders criticized the Continuing Education Exemption for creating inconsistent reporting obligations.

In the Final Rule, CMS acknowledges that including the five specific continuing education organizations in the Continuing Education Exemption inadvertently created an appearance that CMS endorsed or supported those organizations and that the Continuing Education Exemption is ultimately redundant with the Sunshine Act's exemption for indirect payments. Therefore, CMS has decided to delete the Continuing Education Exemption in its entirety, effective as of the 2016 reporting year, which commences on January 1, 2016.

Indirect payments or other transfers of value to Covered Recipients are already exempt from the Sunshine Act's reporting obligations when the manufacturer does not know the identity of the Covered Recipient during the reporting year or by the end of the second quarter of the following reporting year. For example, if a manufacturer provides funding to a continuing education provider that is then given to a Covered Recipient, but the manufacturer does not select or pay the Covered Recipient speaker directly, or furnish the continuing education provider with a distinct, identifiable set of Covered Recipients to be considered as speakers for the event, those payments are excluded from reporting under the Sunshine Act as long as the manufacturer does not know or become aware of the identity of the Covered Recipient prior to the third guarter of the following reporting year.

By providing heightened guidance on the application of the Sunshine Act's indirect payment provision to continuing education payments and deleting the Continuing Education Exemption, CMS expects that the Final Rule will promote more consistent reporting requirements for manufacturers and Covered Recipients. CMS will accept comments on the Final Rule until December 30, 2014.

FEDERAL GOVERNMENT AND NEW YORK REJECT MOUNT SINAI'S 60-DAY RULE ARGUMENTS

On November 10, 2014, the federal government and the state of New York each filed a memorandum in opposition to Mount Sinai Health System's (Mount Sinai) motion to dismiss a False Claims Act (FCA) suit, alleging that Mount Sinai failed to comply with the 60-Day Rule by knowingly retaining Medicaid overpayments. Mount Sinai previously sought to dismiss the suit, in part, on the basis that the complaint failed to properly determine the point at which overpayments were "identified," a requirement for liability

under the 60-Day Rule and the FCA.

In its memorandum, the federal government argues that Mount Sinai chose not to conduct a thorough investigation into receiving potential overpayments and, thus, cannot claim that the overpayments were not identified for the purposes of the 60-Day Rule. The federal government argues that the Centers for Medicare and Medicaid Services (CMS) has indicated that providers cannot avoid their obligation to return overpayments by deciding not to investigate information regarding potential improper payments. For purposes of the 60-Day Rule, the government argues that an entity has "identified" an overpayment when it has determined, or should have determined through the exercise of reasonable diligence, the existence of an overpayment. In its complaint, the government alleges that Mount Sinai knowingly retained overpayments in violation of the 60-Day Rule because it recklessly disregarded information regarding potential overpayments; therefore, such overpayments constituted obligations under the FCA.

We will continue to monitor this case and advise our readers of further developments.

Please contact any member of the <u>Health Law Group</u> at Robinson+Cole if you have questions:

Lisa M. Boyle | Theodore J. Tucci | Leslie J. Levinson | Brian D. Nichols

Pamela H. Del Negro | Christopher J. Librandi | Meaghan Mary Cooper

Nathaniel T. Arden | Conor O. Duffy

Boston | Hartford | New York | Providence | Stamford | Albany | Los Angeles | New London | Sarasota | rc.com

© 2014 Robinson & Cole LLP. All rights reserved. No part of this document may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without prior written permission. This document should not be considered legal advice and does not create an attorney-client relationship between Robinson+Cole and you. Consult your attorney before acting on anything contained herein. The views expressed herein are those of the authors and not necessarily those of Robinson+Cole or any other individual attorney of Robinson+Cole. The contents of this communication may contain attorney advertising under the laws of various states. Prior results do not guarantee a similar outcome.