National Association of Chain Drug Stores (NACDS)

Statement on

PROPOSED CHANGES TO REGULATIONS REGARDING PRIVACY OF INDIVIDUALLY-IDENTIFIABLE PATIENT MEDICAL INFORMATION

April 16, 2002

Hearing of the
Committee on Health, Education, Labor and Pensions
United States Senate
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Mr. Chairman and Members of the Senate HELP Committee. The National Association of Chain Drug Stores (NACDS) appreciates the opportunity to submit comments for the record on the proposed changes issued March 27, 2002 by the Department of Health and Human Services (DHHS) to the final patient medical records privacy regulations. *See* 67 Fed. Reg. 14776

NACDS membership consists of nearly 200 chain community pharmacy companies that operate over 34,000 retail community pharmacies Collectively, chain community pharmacy comprises the largest component of pharmacy practice with over 94,000 pharmacists. Chain operated community retail pharmacies fill over 60 percent of 3 billion prescriptions dispensed annually in the United States.

The HIPAA privacy regulations that are set to take effect in April 2003 present operational problems for community pharmacy. Early on, President Bush announced his determination to implement the new regulations, leaving it to HHS to work on issues of concern to the affected parties. NACDS and its members appreciate the interpretative guidance provided by HHS this past July, which clarified how some of the provisions of the final rule applied to community pharmacy. However, the Guidance continued to leave unresolved several issues relating to the workability of these regulations in the community pharmacy setting.

While community pharmacy is dedicated to protecting a patient's privacy, we are concerned that these regulations, without changes, would actually undermine our ability to serve patients efficiently. These regulations, as written, while well intentioned, create significant impediments to providing patients with medications in a timely and convenient manner. NACDS and our industry's leaders have tried to work closely with HHS, Members of Congress, and patient groups to help them understand the impact of these regulations on our industry's ability to provide efficient pharmacy services. We believe that there are workable solutions that both respect the need for privacy and allow patients to receive the service and care they expect.

Modifications to Prior Written Consent Requirement

NACDS is pleased with many of the changes proposed in the regulation, and will be submitting more extensive comments to the Department on many aspects of the proposed rule. One major improvement relates to "patient consent."

Without a change in the regulation, every patient in every pharmacy across America would have been required to sign a prior consent form in order to obtain a prescription, have their doctor call in a prescription, or call in a refill and have it ready upon their arrival. Currently, no state law requires pharmacies or pharmacists to obtain written consent from patients, so this requirement represents a fundamental operational change in how patients interact with pharmacies ***and*** how pharmacies interact with patients. We believe that the presentation of the prescription by the patient provides defacto consent to the pharmacy to fill the prescription. Otherwise, why would the patient present the prescription at the pharmacy?

Under the proposed rule, however, providers would have the option of obtaining prior written consent from patients, or could simply make a good faith effort to obtain a signed written acknowledgement that the patient has obtained the pharmacy's notice of privacy practices. This doesn't have to occur before pharmacies use patient information to provide pharmacy services. Of course, these regulations represent a privacy "floor," and states could create their own, possibly more stringent, consent requirements.

However, the ability of pharmacy to use PHI for treatment, payment, and operations without prior written consent will facilitate the delivery of prescription services without compromising patient privacy. Here are just a few examples of how obtaining prescriptions will be impacted by this change.

- **Filling a New Prescription:** Under the current regulation, pharmacies cannot fill a prescription until a signed, written consent from the patient is on file at the pharmacy. If the patient uses multiple pharmacies, each pharmacy must have a signed, written consent. Under the proposed changes, pharmacies can fill prescriptions without obtaining signed, written consent.

- **Filling a New Prescription Phoned in, Faxed in, or Electronically Transmitted by a Doctor to a Pharmacy:** Under the current regulation, if a signed, written consent is not on file, a parent cannot pick up a prescription for a sick child that might be phoned or faxed in to the pharmacy from the doctor's office as soon as the parent arrives. Also, prescriptions that are electronically transmitted or to the pharmacy cannot be filled until a signed, written consent is on file, significantly reducing the administrative efficiencies and cost savings resulting from this technology. Under the proposed changes, pharmacies can fill prescriptions without obtaining a signed, written consent from the patient, meaning that phoned in, faxed in, or electronically transmitted prescriptions can be waiting for patients when they arrive at the pharmacy.

- **Picking Up a Prescription for a Home-Bound Senior or Disabled Individual:** Under the current regulation, relatives or friends that are sent to pharmacies by seniors to obtain prescriptions might have to return to the seniors' home to obtain their signed written consent before the pharmacy can fill prescriptions. This might result in multiple trips to the pharmacy, causing hassles for the seniors and delays in starting therapy, especially those that live long distances from pharmacies. Under the proposed changes, patients' representatives can drop off and pick up prescriptions for home-bound seniors and disabled individuals without having to first travel back to their homes to obtain their signed written consent to fill the prescriptions.

- **Obtaining Prescription Refills after the Compliance Date**: Under the current regulation, pharmacies cannot refill prescriptions after the compliance date (April 14, 2003) if a signed written consent is not on file. This affects literally billions of existing active prescription refills that are on file in pharmacies. Prescriptions refills for antibiotics, oral contraceptives, high blood pressure medicines, and many other drugs could not be executed by the pharmacist without a signed written consent. With the proposed changes, active prescription refills can be filled after the compliance date without having to provide a signed, written consent to the pharmacy to refill the prescription.

- **Obtaining a Prescription if you live in one state and work in another, or use different pharmacies:** Under the current regulation, if you use a different pharmacy in the same chain, but the pharmacy that has your consent on file is not able to communicate that to the pharmacy that you are using to fill the prescription, then you have to sign another written consent before the prescription can be filled. With the proposed changes, patients do not have to provide signed consent, so all the new pharmacy would have to do is provide a notice of their privacy practices and make a good faith effort to obtain a written acknowledgement from the patient that they have received the notice.

In sum, making "prior written consent" optional for direct treatment providers will eliminate significant hassles for patients and pharmacies in obtaining and providing pharmacy services. This cannot be overstated. Eliminating the prior written consent requirement will alleviate what would undoubtedly be a very confusing, chaotic, and potentially dangerous situation if patients are unable to obtain their medications because they cannot provide a signed written consent to the pharmacy.

Acknowledgement of Privacy Practices Notice

A proposed revision to the privacy rules would require a pharmacy to "make a good faith effort to obtain a written acknowledgement of receipt" of the pharmacy's notice of privacy policies. NACDS agrees that the proposed revision is an improvement over the current prior written consent requirement. However, there are also burdens associated with collecting a signed acknowledgement just as there are burdens associated with collecting a signed consent. We have four suggestions for making this proposed revision more acceptable and less burdensome.

- **Flexibility in Implementation:** First, the Department should give providers flexibility to implement this requirement in accordance with their current practices. The Department should not implement any rules regarding the form or content of the acknowledgement. For example, the Department should clarify that pharmacies can put a one-sentence acknowledgement within the document that patients already sign when they pick up prescriptions. Patients should not be forced to sign multiple documents at the pharmacy counter.

- **Written Acknowledgment May Create Burdens Similar to Consent:** NACDS believes that a signed acknowledgement is unnecessary. Instead, the rules should simply require a good faith effort to make the notice of privacy policies available to customers. It is the notice that is important, not the signed acknowledgement of receipt of the notice. As long as a covered entity ensures that its notice is available to patients, forcing patients to sign an acknowledgement of that availability does not provide additional privacy protection to patients. Similarly, forcing a pharmacy to "document" the reason why an acknowledgement was not obtained will add additional burdens on pharmacies without protecting PHI.

- **Provide Copies of Notices to Patients that Want One:** Third, the proposal would require pharmacies to actually give every customer a copy of the notice of privacy policies, whether or not the customer wants a copy. That will require pharmacies to use significant amount of paper to give written notices to customers, the vast majority of whom will never read the notice. Patients already receive detailed information from pharmacies regarding the instructions for using their prescription drugs, and most patients will not want to be bothered and confused with more detailed paperwork. Rather than have to hand a copy of the notice to every customer, the rules should require a pharmacy to place copies of the notice in a display on the pharmacy counter. Customers who want a copy can take one, but the vast majority of customer who have no interest in the notice would not have to receive one. That would save a great deal of resources, without limiting customer access to the notice.

- **Shorten Notice and Clarify that State Privacy Practices Do Not Have to be Clarified:** The Department should at the least reduce the burden of this requirement by shortening the notice. The notices are too long because they must describe and give examples of all potential uses and disclosures of PHI. For example, the notices must state that a provider may disclose a patient's PHI for purposes of national security or to protect the president, even though the chances of that actually happening are miniscule and there is nothing that the customer could do about it if it did happen. The result is a notice that is too long – the examples we have seen range from 4 to 8 pages. A notice that is too long will not be read by patients. It will also cost pharmacies tens of millions of dollars to print, store and distribute hundreds of millions of copies of such a long document.

Another way to shorten the notice is to delete the requirement that the notice must explain more stringent state privacy laws. Multi-state chains will have to develop and print 50 different notices, and then update and reissue those notices whenever a state court makes a material change to the state laws. This will cause tremendous expense and inefficiency. Pharmacies have millions of customers, and thus would have to issue and reissue millions of copies of their notices. Rather than have to write and continuously revise 50 treatises on state privacy laws, the notice should discuss the HIPAA rights and state that "state law may provide additional privacy protections." This would not harm patient privacy, because we are not suggesting that we should not have to comply with applicable state laws.

Coordination of Compliance Date for Privacy and Security Standards

NACDS also strongly urges that compliance date for both the final privacy regulations and the final security standards also required pursuant to HIPAA be delayed until at least 24 months after the effective date of the rule that is issued last. Implementation of each of these rules requires significant operational and computer system changes. Congress understood that issue when it required the Department to allow a two-year period between adoption of the final rules and enforcement of the final rules. Providers will already face significant operational challenges in implementing the privacy protections, since we are unlikely to know the final provisions of the regulation until sometime this summer. That would provide less than one full year to prepare for implementation.

Given that the privacy standards and the security standards are supposed to work together, and there is no indication as to when the security regulations will be published as final, it will be exceedingly challenging to plan implementation of the privacy standards without knowing the security standards. Pharmacies should have the opportunity to concurrently assess the impact of both the security standards and any new privacy protections on their operations, and make the necessary changes at the same time. We urge Congress to make the changes necessary to give providers time to implement both these significant changes at one time.

Support for Single, National Privacy Standard

While these changes will provide some welcome relief to patients and providers from the burdens of the original final rule, we have to keep in mind that these regulations do not pre-empt state-based privacy laws and regulations. Under the regulation, the more stringent privacy practice will have to apply. For that reason, even if these proposed changes are final, it will still be administratively burdensome for providers that operate in multiple states to both track, interpret and apply each new privacy law or regulation. This is why NACDS supports a single, national privacy standard that can be known and applied across all 50 states. Only Congress can provide for such a standard, but unfortunately didn't do so in the original HIPAA law. We urge Congress to act this year and create this important national privacy standard before providers have to implement changes in their operations and their systems.

We appreciate the opportunity to submit these comments for the record, and ask that the Committee members direct any questions to us about this testimony. Thank you.