# LAW WATCH

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# NEW "E-SIGN" LEGISLATION OPENS THE DOOR TO INCREASED USE OF ELECTRONIC TECHNOLOGY IN THE HEALTH CARE INDUSTRY

On June 30, 2000, President Clinton signed into law the "Electronic Signatures in Global and National Commerce Act" ("E-Sign"). E-Sign declares that electronic records and electronic signatures that are used in any transaction "in or affecting interstate or foreign commerce" have the same legal effect as their paper and handwritten counterparts. The two required elements, a "transaction" that is "in or affecting interstate commerce" will likely be present with most electronic activity related to health care.

## "Transaction" and "Interstate Commerce" Required

**Is there a "transaction?"** Under E-Sign, a "transaction" is merely an action relating to the conduct of business, consumer or commercial affairs between two or more persons. Health-related business and commercial activities are clearly "transactions" under E-Sign, as are electronic communications with a "consumer" (one who obtains "products or services which are used primarily for personal, family or household purposes").

**Is "interstate commerce" involved?** Although some might argue that certain instances of health care are entirely local, those instances are increasingly rare because those who pay for health care, or who manufacture health-related devices, supplies and pharmaceuticals, operate on a national or international basis. Furthermore, "interstate commerce" seems more likely to be tied to electronic transactions than to their paper-based counterparts. Nonetheless, the tie to interstate commerce should be considered before relying on E-Sign to provide legal validity to a particular transaction's electronic documents and signatures.

## Executive Summary

***Action:*** *Recently enacted federal legislation, "Electronic Signatures in Global and National Commerce Act," also known as "E-Sign," gives certain electronic records and electronic signatures the same legal effect and enforceability as their paper-based and handwritten counterparts.*

***Impact:*** *E-Sign encourages e-business, including "e-health" activities, by giving certain electronic records and signatures the same legal significance as their paper-based and handwritten counterparts. E-Sign also eliminates state and federal requirements for retention of paper documents and handwritten signatures. Those interested in electronic data interchange can start planning now to take advantage of this dramatic shift in legal requirements; however, they should be aware that the law does not address critical e-business issues such as data security and verification of identity.*

***Effective Date:*** *October 1, 2000, for electronic record and signature provisions; March 1, 2001 for records retention provisions, with potential for further delay of these provisions to June 1, 2001.*

## E-Sign Voids State and Federal "Handwriting" and "Hard Copy" Requirements

In addition to establishing the legal validity of electronic transactions, E-Sign voids government-imposed requirements that a document be on paper or printed as a hard copy. Furthermore, E-Sign does away with laws that require documents to be "hand-signed" or be signed "in writing" or in the signer's "own handwriting." These paper and handwriting requirements appear frequently in state and federal laws related to health care. Examples are given below. With E-Sign now on the law books, these state laws and federal agency regulations will be gutted as of October 1.

It is important to note that while E-Sign eliminates governmental prohibitions against electronic signatures and records, it does not force private parties to accept electronic signatures and records. By removing governmentally-imposed barriers to electronic signatures and records and declaring them legally enforceable, E-Sign enables but does not force the private sector to move transactions on-line.

## Electronic Record-Keeping Provisions Delayed

E-Sign also declares that any record-keeping requirement related to transactions involving interstate commerce may be met by keeping electronic records, provided that the electronic record accurately reflects the information to be retained, and remains accessible to all who have a right to see the information. An electronic record which meets these two criteria satisfies a requirement that the "original" record be kept.

E-Sign delays its record retention provisions in order to allow state and federal agencies to revise their record retention rules. Consequently, any federal or state law requiring paper or hard copy records retention will remain in effect at least until March 1, 2001, with the opportunity for an extension until June 1, 2001 for those agencies that are working on but have not completed rulemaking activities related to records retention.

## Consumer Protections

E-Sign includes several consumer protections which must be followed when the transaction involves a consumer (one who obtains "products or services which are used primarily for personal, family or household purposes"). For example, the consumer has the right to give (or refuse or withdraw) something akin to "informed consent" prior to participating in an electronic transaction. If the consumer protection provisions are required for a specific transaction but not followed, the legal validity that E-Sign gives to electronic documents and signatures may be lost for that transaction.

## Exceptions to E-Sign's Preemption of State Law

Certain categories of laws are not preempted by E-Sign. For example, laws governing the creation and execution of wills, codicils, or testamentary trusts are not preempted, so that legal requirements for execution or retention of paper records and for handwritten or original signatures will remain in effect. It is unclear at this time whether the exception extends to living wills and powers of attorney for healthcare; resolution of this ambiguity may depend on the specific language of each state's laws. E-Sign preempts only certain sections of a state's version of the Uniform Commercial Code ("UCC") (for example, the sections relating to sales and leases).

## Examples of "Hard Copy" and "Handwriting" Requirements in Health Care Laws

Following are a few examples of the types of state and federal requirements that E-Sign will affect:

**DEA Prescription Requirements**: Regulations of the Drug Enforcement Administration (DEA) currently state that a prescription for a Schedule II drug may only be filled upon presentation of a written prescription signed by the practitioner. According to the DEA, a Schedule II prescription may be faxed, but the controlled substance may not be dispensed until the pharmacist reviews the written and signed original prescription. Many state laws reiterate these federal requirements. Under E-Sign, electronic prescriptions and signatures will be deemed to comply with these requirements.

**State Prescription Requirements:** Many states require paper prescriptions and handwritten signatures for all or some categories of pharmaceuticals, or prohibit electronic prescriptions generally, or require that prescriptions be maintained in hard copy with the practitioner's original signature. These requirements will be preempted by E-Sign.

**Medical Records:** Many states require handwritten or stamped physician signatures for discharge summaries, physician orders generally and telephonic orders specifically. E-Sign will preempt these requirements and give legal effect to electronic physician records and signatures for medical records, discharge summaries and other reports; however, in order to take advantage of this change in law the necessary electronic records technology must be in place.

**Consent to Treatment**: E-Sign will preempt state laws that require a patient's "written" consent to treatment. Although E-Sign will remove legal barriers to electronic signatures on consent documents, physicians and private hospitals will not be required to accept such signatures, and will be free to develop their own policies as to when and how to accept them.

**Disclosure of Medical Records:** State and federal laws that require a patient's handwritten consent to release medical records or health information will, under E-Sign, be met by obtaining the patient's electronic signature. However, this transaction will likely also be subject to E-Sign's consumer protections, which require that certain information be given to the consumer about conducting the transaction electronically, and require the consumer's consent to an electronic transaction.

**Medicare Conditions of Participation:** Medicare's conditions of participation for hospitals currently mandate that all orders be in writing and signed by a practitioner responsible for the patient. Under E-Sign, hospitals may fulfill this requirement by allowing the use of electronic signatures on orders, if they choose to do so.

## Options for State Governments and Federal Agencies

Although E-Sign summarily disposes of their paper and handwriting requirements, and requires them to use or accept electronic transactions (except with respect to contracts they are a party to), it does not completely ban state and federal agencies from regulating electronic transactions. These agencies will still have several defensive moves available.

First, E-Sign preserves requirements that records be filed with a government agency or self-regulatory organization (for example, the Joint Commission on Accreditation of Health Care Organizations) in accordance with specified standards or formats.

Second, E-Sign allows state and federal agencies to "interpret" E-Sign's provisions through regulations. However, such regulations must be consistent with E-Sign, cannot add to its requirements, must be backed by "substantial justification," must be substantially equivalent to requirements for non-electronic records, cannot impose unreasonable costs, and cannot favor a particular type of technology (such as digital certificates). This last requirement does not apply to state or federal government procurement activities. It remains to be seen how agencies will "interpret" E-Sign without "adding to its requirements."

Third, a state or federal agency may specify performance standards related to the retention of electronic records and signatures, such as standards to

assure accuracy, record integrity, and accessibility of retained records. With these standards the state or federal agency may even require a specific technology (but not specific hardware or software) to be used, as long as the requirement will help to achieve "an important governmental objective." And the agency may go so far as to require record retention in tangible or printed paper form, but only if the requirement is essential to protect a "compelling government interest relating to law enforcement or national security."

Fourth, E-Sign requires government agencies to agree to use or accept electronic records and signatures, **except** "with respect to . . . a contract to which [the agency] is a party." In other words, the agency may refuse to use electronic signatures for the transmission, signing and retention of the agency's own contracts.

Despite these concessions, E-Sign specifically and emphatically prohibits the reimposition of tangible or paper records requirements (except for compelling law enforcement or national security reasons). E-Sign has consequently been perceived by some in state government as an assault on states' rights, so much so that the chief information officers of the 50 states reportedly met in early August to consider obtaining an injunction against the law. As of this writing, no lawsuit has yet been filed.

The Office of Management and Budget is working on draft guidance for federal agencies with respect to E-Sign. The Department of Health and Human Services is also reportedly studying how E-Sign will interact with its regulations under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations are intended to simplify electronic data interchange in health care claims processing transactions, and protect the privacy and security of those transactions. Other state and federal agencies have begun analyzing E-Sign's impact on issues under their jurisdiction, but the short time period between signing of the law and its effective date (90 days) means that some state and federal agencies may not yet understand E-Sign's impact by the time it becomes effective on October 1, 2000.

## Issues Unresolved by E-Sign

E-Sign leaves unaddressed some very important issues related to electronic signatures. For example, E-Sign's definition of "electronic signature" includes any electronic sound, symbol or process with which someone "intends" to sign an electronic record. While this leaves room for the development of new signature technologies, there will be confusion as the world experiments with differently configured electronic signature forms.

Furthermore, E-Sign is silent on whether or how an electronic signature should demonstrate a relationship to the alleged signer. Under E-Sign, one could merely type "X" at the end of a document as one's electronic signature; however, the recipient of the message might not be comfortable relying upon that signature. Digital certificates currently provide proof of the signer's identity, but E-Sign prohibits government agencies from requiring a specific technology. Parties to electronic transactions should therefore address in their contract negotiations their requirements for electronic signatures and procedures for keeping electronic transmissions secure.

## Getting More Information

If you have questions about E-Sign or its applicability, please contact **Robyn Meinhardt** in our Denver office, **Jim Kalyvas, Mike Overly** or **Karen Weinstein** in our Los Angeles office, **Rich Fischer** in our Chicago office, **Christina Kennedy** in our Orlando office, **Paula Ohliger** or **Shirley Paine** in our San Francisco office, or the member of the firm who normally handles your legal matters.

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